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ETHYLENE DIBROMIDE: POSITION DOCUMENT 2/3

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U.S. ENVIRONMENTAL PROTECTION AGENCY

EPA/SPRD-81/74

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EXECUTIVE SUMMARY

This Position Document (PD) 2/3 proposes several regulatory actions to reduce the human health risks resulting from registered pesticidal uses of ethylene dibromide (EDB). These proposed actions are based on the Agency's determination that certain uses of EDB result in unreasonable adverse effects to man. The Agency requests registrants and interested parties to review the proposed actions and the evaluations upon which they are based, and to provide comments or any additional relevant information. All of the registered uses of EDB have been examined in this document. These include: preplant fumigation of soil (to control nematodes); fumigation of stored grains (to control insects); spot fumigation of grain milling machinery (to control insects); post-harvest fumigation of citrus, tropical fruits, and vegetables under USDA Animal, Plant and Health Inspection Service (APHIS) quarantine (to control fruit flies); fumigation of felled logs (to control bark beetles); fumigation of stored beehive supers and honeycombs (to control the greater wax moth); vault-fumigation of stored furniture and clothing (to control various pests); treatment of plants, soil and grass sod in accordance with the USDA/APHIS Japanese Beetle Quarantine Program; and fumigation beneath concrete slab foundations of buildings and porches to control subterranean termites, and spot fumigation of their galleries to control drywood termites.

The first regulatory action the Agency is proposing is to allow registration to continue for preplant soil fumigation, the largest volume use of EDB. However, the Agency will permit this use only if certain restrictions are implemented and additional data requirements are fulfilled. Specifically, the Agency will require applicators to wear respirators and protective clothing; reentry into a treated field will also be prohibited for 24 hours following fumigation. The Agency is also requiring soil fumigant registrants to conduct studies to determine if this use results in groundwater contamination. The need for these studies is based on the concern that EDB is structurally similar to dibromochloropropane (DBCP), a chemical also used as a preplant soil fumigant, which has been found in many groundwater supplies. In addition, the Agency will require registrants to provide data to demonstrate that residues of EDB in crops grown in EDB fumigated soils at maximum allowed application rates do not exceed the limits of sensitivity of analytical methodology (currently 1 ppb). When results from these investigations are available, the Agency will reexamine the adequacy of its regulatory measures for this use.

Second, the Agency is proposing to cancel the EDB registrations for two other major uses: fumigation of stored grains and spot fumigation of grain milling machinery. The bases for these proposed cancellations are that the public health risks of cancer, heritable genetic damage, and reproductive disorders outweigh the economic benefits of these uses. The Agency has concluded that residues of EDB contaminate the human diet as a result of these registered uses. Applicators, persons near a treatment site and workers who handle treated commodities are also exposed to significant levels of EDB via inhalation and dermal contact.

Third, the Agency is proposing that on July 1, 1983, EDB registrations for post-harvest fumigation of citrus, tropical fruits and vegetables will be cancelled. The interim period of allowed use will give time for the development and implementation of efficacious alternatives. There are currently no effective means of protecting these commodities from fruit fly infestations other than EDB. However, gamma irradiation treatment methods are currently being considered. These have been used successfully in several foreign countries.

Fourth, the Agency is proposing to cancel the EDB registration for fumigation of felled logs, a relatively low volume use. The basis for this action is the Agency's determination that the potential risks to applicators outweigh the economic benefits of this use. Based on the current application methods for this use, the Agency has concluded that applicators may be at risk of incurring unreasonable adverse effects resulting from dermal contact and inhalation of EDB vapors. Because the use of the registered alternative endosulfan would result in a national reduction in treatment costs, the Agency has established that there are no benefits for this use of EDB.

Fifth, the Agency is proposing to defer the decision on the use of EDB for control of termites, but in the interim will reinforce and expand current label directions by requiring that it be used only by certified commercial applicators; that applicators must wear protective clothing and a respirator; that premises be vacated by non-applicators during fumigation and subsequent aeration; and for use against subterranean termites, that injection holes be plugged temporarily during, and sealed permanently after, treatment. The Agency defers further regulatory action on uses against termites until EDB can be considered in a "cluster analysis" together with all other pesticides used for control of subterranean and drywood termites (including aldrin, dieldrin, chlordane, heptachlor, pentachlorophenol, chlorpyrifos, methyl bromide, sulfuryl fluoride, hydrogen cyanide, and silica aerogel).

Finally, for the remaining uses: fumigation of beehive supers, vault fumigation of stored clothing and furniture, and the USDA's Japanese Beetle Quarantine Program, the Agency is proposing to allow these uses to continue only if certain use restrictions are implemented and additional data requirements are fulfilled. Specifically, the Agency will require protective clothing and other low-cost measures designed to reduce applicator exposures to EDB. In addition, the Agency will require registrants of products with each of these uses to conduct studies to determine the EDB air levels to which applicators are exposed, the number of applicators involved in these uses, and the amounts of EDB applied annually for these uses.

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I. Introduction

A. General Background and Organization

The Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA), requires the Environmental Protection Agency (EPA) to review the risks and benefits of the uses of pesticides suspected of causing adverse effects to human health or the environment. On December 14, 1977, EPA issued a Notice of Rebuttable Presumption Against Registration and Continued Registration (RPAR) of pesticide products containing ethylene dibromide (EDB), a fumigant insecticide and nematocide. The rebuttable presumption was based on validated studies showing that EDB is oncogenic and mutagenic, and has adverse reproductive effects on several species of animals. Since then EPA has reviewed rebuttal comments and conducted thorough risk and benefit analyses of the pesticidal uses of EDB.

This document determines what regulatory actions EPA should take under FIFRA to change the current use patterns of pesticides containing EDB. Included are discussions about the risks and benefits of the pesticidal uses of EDB, and explanations about the rationale for the Agency's proposed final decision. This document is written in five chapters. Chapter I is this introductory section. Chapter II summarizes and evaluates the comments received on the RPAR, evaluates the potential health risks of EDB, and briefly describes the laboratory evidence of toxicity, available exposure data, available epidemiology data and the Agency's revised risk assessment. Chapter III summarizes the use-by-use economic benefits of EDB and the assumptions and limits of these estimates. Chapter IV describes possible regulatory options for the reduction of risks. Chapter V evaluates the risks and benefits and adverse impacts of each possible action for each of the nine general categories of the registered uses of EDB, and selects the regulatory action the Agency is proposing for each use.

B. Legal Background

1. The Statute

The FIFRA (7 U.S.C. Section 136 et seq.) regulates all pesticide products. Under Section 12(a)(1)(A) of FIFRA all pesticide products must be registered before they may be sold or distributed. Before a pesticide may be registered, the Administrator must determine that its use will not result in "unreasonable adverse effects on the environment," which is defined by Section 2(bb) of FIFRA to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." In sum, any decision to register or continue to register a pesticide must weigh both the risks and the benefits from the use of the pesticide.

Section 6(b) of FIFRA authorizes the Administrator to issue a notice of intent to cancel the registration of a pesticide or to change its classification if it appears to him/her that the pesticide or its labeling "does not comply with the provisions of [FIFRA] or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment."

Table 1. Physical Properties of EDB 1/

Boiling Point	--	131.5°C
Melting Point	--	9.3°C
Vapor Pressure	--	11.0 mm Hg @ 25°C
Specific Gravity	--	liquid (water @ 4°C =1) 2.172 @ 20°C gas (air =1) 6.487
Solubility	--	0.43 g/100 g water @ 30°C, soluble in ethanol, ether and most organic solvents.
Stability	--	Stable
Flammability	--	Nonflammable
Appearance	--	Colorless liquid
Heat of Vaporization	--	46.2 cal/g
Corrosiveness	--	vapor or liquid attacks many paints and some metals (especially aluminum)
Flash Point	--	None
Fire Point	--	None
Weight & Volume	--	1 U.S. gallon = 18.11 lbs.
Conversions	--	1 U.S. gallon = 8.215 kg.
	--	1 lb. liquid = 208 ml @ 25°C
	--	1 oz/1000 ft^3 = 1 mg/liter = 1 gm/m^3
	--	1 ppm = 7.69 mg/m^3
	--	1 mg/m^3 = 130 ppb
Density of EDB in saturated air	--	1.08 (air = 1)
Conc. of EDB in air at saturation	--	1.3% by vol. @ 20°C

1/ Data taken from several sources including Monro (1969), Thomson (1977), Martin (1971), Spencer (1973), Merck (1976).

The Administrator may also cancel the registration of a pesticide if its labeling does not comply with the misbranding provisions of FIFRA which require the labeling to contain language "adequate to protect health and the environment" [FIFRA Section 2(q)].

2. The RPAR Process

The purpose of Rebuttable Presumption Against Registration (RPAR) is to gather risk and benefit information about pesticides which appear to pose risks to health or to the environment. As described in 40 CFR 162.11, this process is designed to allow an open, balanced decision with participation by all interested groups. The RPAR regulations describe various risk criteria, and provide that an RPAR shall arise if the Agency determines that any of the risk criteria have been met. Once a notice of rebuttable presumption is published, registrants, applicants and interested persons may submit evidence in rebuttal or in support of the presumption. All parties may also submit evidence on the economic, social and environmental benefits evidence of any use of the pesticide. If the presumptions of risk are not rebutted, the evidence of the benefits from use of the pesticide submitted to or gathered by the Agency must be evaluated and considered with the risk information. The Agency analyzes various risk reduction methods and their costs. The Agency then determines whether or not the risks of pesticide use may be outweighed by its benefits. If a balance between risks and benefits cannot be reached for a specific use, the registration for that use must be canceled or otherwise restricted, or, in the case of a new application, denied.

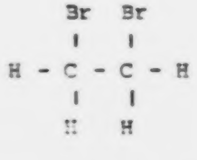
C. Chemical Background

1. Nomenclature

Ethylene dibromide (EDB) is the common name for 1,2-dibromoethane, CAS number 0001060934. It is a soil and commodity fumigant having both nematocidal and insecticidal use. The term EDB as used in this document refers specifically to the organic molecule, ethylene dibromide, and does not include its breakdown products, such as inorganic bromide(s) or total bromide(s). These latter two terms are used in the food additive tolerances (21 CFR 123) and raw agricultural commodities tolerances (40 CFR 180).

2. Chemistry

At room temperature, pure EDB is a colorless, heavy, nonflammable liquid. It is prepared commercially by reacting bromine with ethylene gas and has a characteristic mildly sweet odor detectable in air at levels ranging from 10 to 25 ppm (77 mg/m^3 to 192.5 mg/m^3). Its chemical formula is CH_2BrCH_2Br, its molecular weight is 187.88, and its structural formula is:



$$\begin{array}{ccccccc} & & Br & & Br & & \\ & & | & & | & & \\ H & - & C & - & C & - & H \\ & & | & & | & & \\ & & H & & H & & \end{array}$$

Table 1 lists other chemical and physical properties of EDB.

3. Uses and Registration

EDB has been produced in the United States since the 1920's and used primarily as a lead scavenger in leaded antiknock gasoline additives. Because of the Agency's regulations requiring a phase-out of leaded gasoline, this use of EDB has steadily dropped over the last few years and is expected to eventually become negligible.

During the 1950's and 1960's, federal pesticide registrations for uses of EDB as a fumigant were granted under FIFRA. Currently, the major registered pesticidal uses of EDB are:

- o Pre-plant soil fumigation by injection for a wide variety of food and non-food crops including vegetables, fruits, grains, peanuts, cotton, and tobacco;
- o Post-harvest commodity fumigation for grains, fruits and vegetables, including various State, Federal or international quarantine programs on citrus, fruits, nuts, and vegetables;
- o Fumigation of grain milling machinery and flour mills to control insect infestations in milling remnants and processed milled products.

Other uses of EDB include:

- o Control of wax moths in beehive supers;
- o Control of mountain pine bark beetles in the western states by Federal and State forestry agencies;
- o Control of drywood and subterranean termites in structural pest control operations;
- o Control of clothes moths, dermestid beetles and similar pests of furs, rugs, and other items in fumigation vaults; and
- o Control of Japanese beetles in the soil of balled ornamental trees and shrubs under the APHIS Quarantine Program.

EDB is usually formulated as a liquid concentrate or as a gel. There are 122 federal pesticide registrations, held by 53 registrants, of products containing EDB as an active ingredient, and 24 state registrations, held by 12 registrants. In addition, emergency exemptions for EDB use on soybeans (discussed in detail in the next section) were granted to six states early this year for use through the month of July, 1980. There are no Federally registered products containing EDB as an inert ingredient. Most of the registered products are mixtures of EDB and other active ingredients, such as carbon tetrachloride, ethylene dichloride, methyl bromide, chloroform, carbon disulfide, sulfur dioxide, chloropicrin, and benzene.

The Agency (Holtorf, 1980) estimates that about 340-360 million pounds of active ingredient EDB are produced annually in the U.S. by four basic producers: Dow Chemical, Ethyl Corp., Great Lakes Chemical and PPG

TABLE 2. EDB (Inorganic Bromide) Tolerances and Exemptions from Tolerance.

Commodity	Tolerance	Citation and Form
Soil Fumigation Uses		
Broccoli	75 ppm	40 CFR 180.126
Carrots	"	Inorganic bromides
Melons	"	(calculated as Br)
Parsnips	"	
Potatoes	"	"
Eggplants	50 ppm	"
Okra	"	"
Summer Squash	"	"
Sweet Corn	"	"
Sweet Corn Forage	"	"
Sweet Potatoes	"	"
Tomatoes	"	"
Pineapples	40 ppm	"
Cucumbers	30 ppm	"
Lettuce	"	"
Peppers	"	"
Cottonseed	25 ppm	"
Peanuts [1]	"	"
Asparagus	10 ppm	"
Cauliflower	"	"
Lima Beans	5 ppm	"
Strawberries	"	"
Post-Harvest (Commodity) Fumigation Uses		
Barley [2]	50 ppm	40 CFR 180.146
Corn	"	Inorganic bromides
Oats	"	(calculated as Br)
Popcorn	"	"
Rice	"	"
Rye	"	"
Sorghum (milo) [2]	"	"
Wheat	"	"

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[1] 40 CFR 180.126(a) prohibits use of treated peanut hay and hulls as feed for meat and dairy animals.

[2] 40 CFR 180.1006 exempts these grains from the requirement of a tolerance for organic bromide residues of EDB.

Table 2 - continued

Commodity	Tolerance	Citation and Form
Quarantine Fumigation Uses		
Beans (String)	10 ppm	40 CFR 180.146
Bitter Melons	■	Inorganic bromides
Cantaloupes	■	(calculated as Br)
Cavendish Bananas	■	■
Citrus Fruits	■	■
Cucumbers	■	■
Guavas	■	■
Litchi Fruit	■	■
Litchi Nuts	■	■
Longan Fruit	■	■
Mangoes	■	■
Papayas	■	■
Peppers (Bell)	■	■
Pineapples	■	■
Zucchini Squash	■	■
Cherries	25 ppm	40 CFR 180.146
Plums (Fresh Prunes)	■	Total inorganic and organic bromides
Food Additive Tolerances		
Milled Grain Fractions	125 ppm	21 CFR 193.225 1977 Inorganic bromides (Calculated as Br) from all fumigation sources including grain-mill machinery.
Fermented Malt Beverages from corn grits and cracked rice	25 ppm	21 CFR 193.230 (d) (1977) Total inorganic bromides (calculated as Br) from all fumigations with bromine compounds.

Table 2 continued

Commodity	Tolerance	Citation and Form
Dried Eggs	400 ppm	21 CFR 193.250 Total inorganic bromides from all organic bromides used as a soil, commodity, or processed food fumigant (calculated as Br).
Parmesan and Roquefort Cheese	325 ppm	"
Concentrated Tomato Products	250 ppm	"
Dried Figs	"	"
Processed Foods (including processed grain and cereal products)	125 ppm	"
Milled Fractions in Animal Feeds from barley, corn, grain sorghum (milo), oats rice, rye, and wheat	125 ppm	21 CFR 561.260(b) Inorganic bromides (calculated as Br) resulting from carry over or concentration of residues from fumigation of grains with MBr or EDB.

Industries. The bulk of this production, about 230 million pounds, is used as a gasoline additive. Pesticide usage of EDB in comparison to total production is quite small, comprising about four percent or 13 to 15 million pounds of annual U.S. production. Estimates of quantities imported and exported for pesticide usage are considered confidential and are not publicly available. The major pesticide uses of EDB are dominated by agricultural soil fumigant use, comprising about 90% of U.S. consumption. The remaining 10% is used for commodity and space fumigation.

D. Regulatory History

1. Tolerances

There are no tolerances for EDB *per se* in or on raw agricultural commodities because it had been assumed, on the basis of data originally submitted by petitioners, that there would be no EDB residues. This conclusion was based on the hypothesis that the parent EDB compound had either completely evaporated or been converted to bromide ions which were subsequently taken up by plants as inorganic bromides. Residue analyses then available for EDB in crops grown in treated soil were negative for the organic molecule. The analytical method for organic bromide, employed from about 1950 through 1965, had a sensitivity of only 0.2 to 1.0 ppm and was not specific for EDB, but rather measured only the organic bromide ion. Consequently, tolerances were established in 40 CFR 180 for inorganic bromides resulting from the use of EDB in or on raw agricultural commodities, and as a food additive in processed foods by 21 CFR 193 and 561. These tolerances are presented in Table 2.

2. Pre-RPAR Actions

On October 16, 1974, the National Cancer Institute (NCI) issued a "Memorandum of Alert" describing a preliminary finding of EDB's carcinogenic activity in rats and mice. On the basis of this information,the Agency began a general review of the production and use status of EDB.

On July 14, 1975, the Environmental Defense Fund (EDF) petitioned the Agency to investigate EDB on a priority basis and to take suspension or cancellation action against the compound, as justified (Butler, 1975). In November, 1975, EDB was accepted by the Office of Special Pesticide Review as an RPAR candidate, based on the final NCI study which showed EDB to be carcinogenic in both rats and mice. After this initial petition, EDF amended and renewed its request for action against EDB under FIFRA on January 21, 1976, September 30, 1976, and August 26, 1977 (Hinkle, 1976, 1977).

Additional evidence for this referral included studies showing EDB to be mutagenic and capable of producing adverse reproductive effects in several species of animals. On September 7, 1977, the Agency's Carcinogen Assessment Group issued a Preliminary Risk Assessment for EDB which stated, "There is strong evidence that EDB is likely to be carcinogenic to man" (CAG, 1977).

Following intensive review and validation of the literature, the Agency published a Notice of RPAR and the RPAR Position Document 1 in the Dec. 14, 1977 Federal Register. The basis for the RPAR is the risks to man of oncogenicity, mutagenicity, and adverse reproductive effects as a result of pesticidal exposures to EDB.

3. Post-RPAR Actions

During the initial rebuttal period, December 14, 1977, to January 30, 1978, the Agency received twelve requests for extension of the rebuttal period. The Agency granted an extension to April 3, 1978. During and after the extended rebuttal period, 91 rebuttal submissions were received. After the extension deadline, several rebuttals were amended, resulting in a total of 105 documents in the rebuttal file (Appendix 1). Thirteen of these submissions contained rebuttal information alone or in combination with benefits information. Thirty-four of the submissions provided some type of benefits information only, while an additional thirty-five contained "testimonial" statements of need which were not supported by any data. There were several other submissions, including support for an immediate "ban" or other action against EDB.

Following the 1979 suspension of DBCP as a preplant pesticide for soybean nematode control, several states claimed that there are no other registered pesticides that are economical or effective against nematodes. Based on test results showing EDB to be as efficacious as DBCP, six states applied for temporary permits (e.g., exemptions from FIFRA) to allow this use under section 18(c) of FIFRA. These exemptions were granted for the period beginning April 24, 1980 and ending July 31, 1980, with numerous restrictions to reduce health risks to applicators. Table 3 describes these exemptions in detail.

II. Risk Analysis

The Agency issued the Notice of RPAR and Position Document 1 (PD-1) based on three criteria: oncogenicity, mutagenicity, and reproductive effects. After issuing the RPAR, the Agency began a detailed risk/benefit analysis according to applicable guidelines and policies. This chapter is divided into three sections: Section A evaluates the rebuttal comments the Agency received following the issuance of the PD-1, and discusses the scope and quality of the available toxicological data, including new data obtained since the publication of PD-1; Section B estimates human exposures; and Section C quantifies the potential health risks of EDB to humans.

A. Rebuttal Evaluations and Qualitative Assessment of Risk Data

1. Oncogenicity

In issuing the RPAR, the Agency relied on evidence of oncogenicity reported in an NCI-sponsored study (Weisburger, 1977). This study showed a statistically significant increase in the incidence of squamous cell carcinoma of the forestomach in both rats and mice as compared to the controls. Based on its preliminary review of the data from NCI, the Agency stated:

> .. EDB causes a significant increase in the incidence of gastric carcinomas in both sexes of rats and mice. Metastases of these tumors are reported. The tumor rates appear to be high and the differences are highly significant. (Anderson, 1977).

The Agency's position that an oncogenic rebuttal should arise is based on its evaluation of this study and 40 CFR Section 162.11(a)(3)(ii)(A). This statute states that rebuttable presumption of oncogenicity shall arise if a pesticide "... induces oncogenic effects in experimental mammalian species or in man as a result of oral, inhalation or dermal exposure..." As a further clarification of the provision, the preamble to the Agency's Interim Procedures

Table 3. Emergency Exemptions for EDB Use on Soybeans (4/24/80-7/31/80)

Location of Use/Applicant	Pest	Acreage (Maximum)	Product
Alabama/Department of Agriculture and Industries	Soybean Cyst Nematode Root-Knot Nematode	160,000	Soilbrom 90EC
Florida/Department of Agriculture and Consumer Services	Soybean Cyst Nematode Southern Root-Knot Nematode Peanut Root-Knot Nematode Reniform Nematode String Nematode	130,000	Soilbrom 90EC
Georgia/Department of Agriculture	Soybean Cyst Nematode Peanut Root-Knot Nematode Lance Nematode	98,000	Soilbrom 90EC Dow Fume W-85 Ethylene Dibromide
Mississippi/Department of Agriculture and Commerce	Soybean Cyst Nematode Spiral Nematode	5,000	Soilbrom 90EC
South Carolina/Clemson University	Columbia Lance Nematode	1,000,000	Soilbrom 90EC Dow Fume W-85 Ethylene Dibromide
Tennessee /Department of Agriculture	Soybean Cyst Nematode	2,118,818	Soilbrom 90EC

Restrictions on use for all above exemptions include:

1. Application rate may not exceed 32 lbs/acre/year of EDB active ingredient
2. Application is to be carried out in accordance with the supplemental labeling submitted on April 1, 1980, except use must be limited to pests authorized by this exemption.
3. Applicators and others handling EDB must wear protective clothing and a respirator, unless a "closed system" is used, which prevents applicator contact with EDB.
4. All applicable precautions and restrictions on the registered product label are to be observed.
5. No more than the acreages designated above are to be treated.
6. Soybean hay from treated fields may not be used for feed.
7. Residues of inorganic bromide must not exceed 125 ppm in or on soybeans or 150 ppm in soybean meal. Soybeans with less than 125 ppm and soybean meal with less than 150 ppm inorganic bromide residues may be moved in interstate commerce. The Food and Drug Administration, DHEW, has been notified.

and Guidelines for Health Risk and Economic Impact Assessment of Suspected Carcinogens (May 25, 1976; 41 FR 21402) states that "... a substance will be considered a presumptive cancer risk when it causes a statistically significant excess incidence of benign or malignant tumors in humans or animals."

On the basis of the evidence summarized in Position Document 1, the Agency concluded that the cancer risk criteria had been exceeded by all registrations and applications for registration of pesticide products containing EDB, and that a rebuttable presumption against new or continued registration of such products should arise.

Six respondents (Rebuttal nos. 3C, 47, 48, 64, 78 and 79) addressed rebuttal comments to the oncogenic criterion. The Agency has divided these rebuttals into two broad groupings, those which address uncertainties in extrapolating to man from the laboratory studies conducted on animals, and those studies which investigate the health of workers occupationally exposed to EDB.

a. Response to Rebuttals of Animal Oncogenicity

(1) Direct Response to Rebuttals

The comments addressing the uncertainty of extrapolating from animals to man can be grouped into broad categories:

- o The route of administration, intubation, was inappropriate because human exposure would be primarily by inhalation;

- o Massive doses both obscured detection of a no observable-effect-level (NOEL) and overwhelmed the animals' metabolic and detoxification processes;

- o The forestomach, where tumors occurred in the test animals, is without a counterpart in humans;

- o The oncogenic response at the site of intubation was due to an extreme irritant effect.

The Agency has concluded that the first rebuttal listed above is invalid. Human exposures to EDB also result from its presence in the human diet. At least three uses of EDB result in its presence in the human diet: fumigation of stored grains; "spot" fumigation of grain milling machinery; and postharvest fumigation of citrus, tropical fruits and vegetables.

In addition, the latter part of this section describes recent evidence which demonstrates that EDB is a potent carcinogen in animals following inhalation exposure. Midwest Research Institute (MRI), under a contract with The National Institute of Occupational Safety and Health (NIOSH), found a significant increase in the incidence of tumors of the spleen, mammary gland, adrenals and subcutaneous tissues in a group of rats exposed to 20 ppm of 1,2-dibromoethane alone (Wong, 1979). Most recently, Hazelton Laboratories, under a contract with NCI (1980), also found inhalation of EDB to be causal to a statistically significant increased incidence of cancers in both rats and mice.

The second rebuttal comment, that the massive doses overwhelmed the animals' metabolic systems, obscuring a no-observable-effect-level (NOEL), is one of the most common criticisms of NCI cancer bioassay studies (Mishra, 1978a). It has been argued by the Agency (Mishra, 1978a) and NCI that the use of maximum tolerated dose (mtd) and 1/2 maximum tolerated dose in cancer bioassay (even in the absence of a NOEL) is now accepted by the Agency, and its use has been included in the proposed EPA/OPP oncogenicity testing guidelines. Results from the above-mentioned NCI study (1977) show that mice receiving only 1/2 the mtd experienced extremely high and statistically significant cancer incidence. In addition, results from the NIOSH and NCI-sponsored studies discussed above demonstrate that EDB is carcinogenic in animals at low doses (20 ppm). The Agency's Interim Cancer Guidelines (41 FR 21402) state that in the absence of definitive information to the contrary, any exposure, however small, will incur some risk of cancer on the exposed population. In essence, the Agency position is that there is an assumed cancer risk from chemical carcinogens for any level above zero. The Agency concludes that this rebuttal is invalid.

The Agency also concludes that the third rebuttal is not valid. It is true that humans do not have a counterpart to the forestomach of rats. "However, the site of tumorigenic effect, and the tumor cell type produced by a chemical is known to change depending upon the animal species, dose schedule and routes of administration used. Thus, the absence of forestomach in humans may not make humans immune to carcinogenic effects of EDB." (Mishra, 1978a). This rebuttal is further invalidated by results of the NIOSH study in which inhaled EDB was found to induce tumors of the spleen, mammary gland, adrenals, and subcutaneous tissues.

The fourth rebuttal, that the oncogenic response was due to an extreme irritant effect, is based on the chronic "irritation" theory of carcinogenesis. This general theory that there is high correlation between chemicals which are irritants and are also carcinogens has long been discarded and the evidence against it is summarized in the book Carcinogenesis as a Biological Problem (Berenblum, 1974). Most irritants in mouse dermal tests were noncarcinogenic and the same was true for irritants introduced in subcutaneous and other types of exposure tests. Among the carcinogens which could be described as irritants, there was no correlation between carcinogenic potency of the agent and the degree of irritant injury produced.

(2) Pertinent New Studies

Since the issuance of PD-1, three new studies were completed which investigated the carcinogenic potential of EDB in animals. These are the Dow Chemical Company Rat Inhalation Study, the Midwest Research Institute Rat Inhalation Study, and the NCI Rat and Mouse Inhalation Study.

Dow Chemical Co. Rat Inhalation Study: A final report entitled "13 Week Repeated Inhalation Study on Ethylene Dibromide (EDB) in Male and Female Rats" (Nitschke, 1980) was reviewed by the Agency (CAG, 1980b). The study consisted of exposing male and female CDF (F-344) rats to 0, 3, 10 or 3076 mg/m^3 ethylene dibromide, 6 hours/day, 5 days/week for 13 weeks for a total of 67-68 exposures in 95-96 days. Scheduled sacrifices occurred after 1, 6, and 13 weeks of exposures.

Findings from the study included:

- o rats exposed to 23 mg/m^3 EDB showed no consistent effect in any parameter;
- o at 77 mg/m^3 EDB caused slight epithelial hyperplasia of the nasal turbinates in animals necropsied after 1, 6 or 13 weeks of exposure; however, 88 days after the last exposure to EDB, no morphological difference from control animals was observed;
- o rats exposed to 3076 mg/m^3 EDB showed a definite adverse response characterized by a decrease in body weight gain, an increase in liver and kidney weights, and pathologic effects in the nasal epithelium. The nasal turbinates of rats progressed from very slight hyperplasia of the epithelium to hyperplasia and nonkeratinizing squamous metaplasia.

The Dow report concludes:

While this study has shown that repeated subchronic exposures of rats to 77 mg/m^3 or 3076 mg/m^3 EDB induce pathologic changes in respiratory epithelium of the nasal turbinates, a subsequent post-exposure phase revealed a lack of progress of the lesions with almost complete reversions toward normal histologic appearance of the nasal turbinates. In view of these findings and the lack of any lesions subsequent to repeated exposure to 3 ppm EDB, short-term repeated exposure to these concentrations of EDB would not be expected to result in any long term irreversible effects upon the nasal turbinates or other tissues of the body.

The Agency (CAG, 4/30/80) has reviewed this study, noting the short duration of exposures, and has concluded that this study involved exposures to animals which are clearly too short in exposure duration to be of value in determining chronic risks present from long term exposures to EDB. (CAG, 1980b).

Midwest Research Institute Rat Inhalation Study (Wong, 1979): This study involved significantly longer exposures and lower concentrations of EDB. This 18 month study with Sprague-Dawley rats was designed to assess the carcinogenicity of inhaled ethylene dibromide (EDB) and the effect of dietary disulfiram on the carcinogenic response to ethylene dibromide. For this purpose, the tumor response of four groups of males and females, each with a size ranging from 120-134 animals was evaluated as follows: (1) controls; (2) 154 mg/m^3 of inhaled EDB administered for 7 hrs/day, 5 days/week for 18 months; (3) 0.05% disulfiram in the diet for 18 months, and (4) both EDB and disulfiram.

The preliminary draft report was reviewed by the Agency (CAG, 1979). The project officer, Dr. H. B. Plotnick, stated that although the report is in draft form, the pathological data have been thoroughly reviewed and will not be altered in subsequent versions. The CAG analysis states that, this report permit us to make a direct estimate of the carcinogenic effect of inhaled EDB and frees us from having to rely on the unsatisfactory upper bound estimates previously derived from intubation studies.

The authors of the MRI report found that EDB alone (group 2) and EDB with disulfiram (group 4) produced a statistically significant increase in tumors at several sites, compared to the group of controls. The sites are listed below.

	EDB		EDB & Disulfiram	
	Males	Females	Males	Females
Spleen hemangiosarcoma	*	*	*	*
Adrenal tumors	*	*	*	*
Liver hemangiosarcoma	X	X	X	*
Liver hepatocellular carcinoma	X	X	*	*
Mesentery hemangiosarcoma	X	X	*	*
Kidney renal tumor	X	X	*	*
Subcutaneous tumors	X	X	X	X
Thyroid tumors	X	X	*	*
Mammary tumors	-	*	-	*
Lung tumors	X	X	*	X

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* denotes statistically significant increase, $p<0.05$
X denotes not statistically significant
- not applicable

Thus, this study demonstrates that EDB is also carcinogenic in rats following prolonged inhalation exposures. "A high mortality rate and a significant increase in the incidence of tumors of the spleen, mammary gland, and adrenals was noted in the group [of rats] exposed to 154 mg/m^3 1,2-dibromoethane alone." (Plotnick, 1980).

National Cancer Institute Rat and Mouse Inhalation Study (NCI, 1980): The possible carcinogenicity of 1,2-dibromoethane in rats and mice was tested by Hazelton Laboratories of America, Inc., and published recently in a cancer bioassay under a contract sponsored by the National Cancer Institute (NCI).

In the rat study, 50 F344 rats of each sex were exposed to 77 or 3076 mg/m^3 of 1,2-dibromoethane by inhalation 6 hours/day, 5 days/week for a maximum of 103 weeks. Untreated control groups comprised of 50 rats of each sex were exposed in chambers of ambient air.

The body weights of the rats were monitored throughout the study. The mean body weights of the high exposure group of either sex were lower than those of the corresponding untreated controls. Survival periods in the high-dose rats of both sexes were shorter than in the controls.

The histopathologic examination of all the major tissues and organs revealed a statistically significant increase in the incidences of carcinomas, adenocarcinomas, adenomatous polyps of the nasal cavity, and hemangiosarcomas of the circulatory system in male and female rats exposed to a 3076 mg/m^3 dose level as compared to the controls.

In addition, a statistically significant increase in tumor incidences of the following organs of rats was observed: adenomas of the pituitary in low-dose rats of either sex when compared with the corresponding controls; and alveolar/bronchiolar adenomas or carcinomas and fibroadenomas of the mammary gland in high-dose female rats when compared with the corresponding controls.

In summary, 1,2-dibromoethane was carcinogenic for F344 rats. These results confirm the carcinogenic effect observed in the NIOSH study in Sprague-Dawley rats tested by Midwest Research Institute.

In the mouse study, fifty B6C3F1 mice of each sex were exposed to 77 or 3076 mg/m^3 of 1,2-dibromoethane by inhalation 6 hours/day, 5 days/week, for a minimum of 78 weeks. Untreated control groups consisting of 50 mice of each sex were exposed in a chamber to ambient air. Throughout the study, mean body weights of high-dose mice of either sex were lower than the controls. Survival of the low and high-dose female mice was significantly shorter than survival for the corresponding controls.

The histopathologic examination of all major organs revealed statistically significant incidences of alveolar/ bronchiolar adenomas or carincinomas in high-dose male mice as compared to the corresponding controls. In high-dose female mice, the incidences of hemangiosarcomas of the circulatory system, fibrosarcomas of the subcutaneous system, carcinomas or adenomas of the nasal cavity, and adenocarcinomas of the mammary gland were significantly higher than those in the corresponding controls.

In summary, 1, 2-dibromoethane induced a carcinogenic effect in male and female B6C3F1 mice. The Agency (CAG) will extensively review this study and evaluate data for possible use in the quantitative risk assessment for human population exposure to 1,2-dibromoethane via inhalation.

(3) Conclusion - Animal Oncogenicity of EDB

On the basis of the discussion presented above, the Agency concludes that the presumption of oncogenic risk as stated in PD-1 has not been rebutted, because no respondent to that notice has sustained the affirmative burden of proof set forth in 40 CFR 162.11(a)(4). In providing an assessment of the "weight" or meaning of the available studies on oncogenicity of EDB to animals, the Agency concludes that EDB is a potent animal oncogen.

b. Response to Rebuttals of Human Oncogenicity of EDB:

In response to the human oncogenic potential of EDB, one respondent (Rebuttal No. 3c) submitted three studies which investigated the health of workers exposed to EDB. Each of these studies is summarized below, together with the Agency evaluation.

(1) The Mortality Experience of 161 Employees Exposed to Ethylene Dibromide in Two Production Units (Ott,1977)

This study was undertaken to investigate the mortality experience of persons occupationally exposed to EDB in two manufacturing units. The emphasis of the study was on cancer mortality and cancer due to respiratory disease. The total cohort population consisted of 161 employees from both units.

The estimated EDB exposure and duration of exposure ranged from 1-96 ppm and 1-16 years respectively. In both Units I and II, employees were also exposed to several other potentially toxic chemicals, such as vinyl chloride, carbon tetrachloride, benzene, nickel acetate and silica. The study did not mention the exposure levels or duration of exposure of employees to these and numerous other chemicals. In addition, a number of employees in Unit II were exposed to arsenic, a known carcinogen.

The investigators reported that no increased malignancy was noted in Unit I. The observed cancer incidence was 1 case against 3.6 expected. The deaths from all causes were not elevated over expected deaths. In Unit II, after excluding the workers exposed to arsenic, a slight increase in both cancer deaths and deaths due to respiratory diseases were observed. A total of 5 cases of malignant tumors were observed in contrast to the expected incidence of 2.2 ($p=0.072$). Two of these 5 cases were stomach cancers against an expected incidence of 0.7 ($p = 0.150$). The remaining 3 cancer cases were also higher relative to 0.9 cases expected ($p = 0.063$). The investigators concluded that, because of the limited size of the study population and the variety of toxic agents to which individuals in Unit II may have been exposed, it would be difficult to interpret these findings as being demonstrative of effects of EDB specifically, or any other specific toxic agent.

In submitting this study, the rebuttors noted that it was of doubtful significance (Great Lakes Chemical Co., 1977). The Agency has concluded the following:

"This study shows slight increases in stomach cancer incidence and deaths due to all causes; however, this may not be solely attributed to EDB exposure alone, since workers were also exposed to other chemicals, and that two cancer deaths occured in the same family (father and son)." (Mishra, 1978a)

(2) The Associated Octel Company Ltd: A Mortality Survey on Employees at an Ethylene Dibromide Plant at Hayle, England (Turner, 1977)

The study investigated the death rates of 117 persons occupationally exposed to EDB where employment was known to exceed 4 years. Rates per 1000 man years were compared between EDB workers and the population of southwest England. The number of man years in the four groups in the age range of 25 to 44, 45 to 64, 65 to 74, and 75 and over, were 1797, 1440, 177, 67 respectively. The author claims that when these groups were compared with the population in southeast England, there was no observed increased incidence of cancer deaths in the workers exposed to EDB.

No monitoring or exposure levels of EDB in the plant are discussed. Without knowing the exposure levels of EDB, the Agency is unable to use this study to assess the human oncogenic potential of EDB. (Mishra, 1978a).

(3) Dibromoethane: A Survey of Employee Records at Amlwch Factory (Turner, 1976).

This study was a retrospective investigation of the mortality experience of workers occupationally exposed to EDB at a manufacturing plant in southwest England. The health records of the personnel employed at the factory during the period from 1952 to 1975 were examined. These employees were an unusual group, in that they were preselected for employment on the basis of above average health. Of the 297 employees known to have worked at the site, a cohort of 273 persons was accounted for and used in the study.

Ambient air levels of EDB in the plant were not given. Although the duration of exposure of the entire cohort was not determined, the investigators reported that the 31 men, who died by the end of 1975, had worked on the site an average of 13 years.

The average age of the group was 40 years. Mortality rates for the entire cohort were calculated and were compared to the death rate for males in an unexposed population in the 45-64 age group in the area in which the Amlwch Factory was located. The average ages of the test and control groups differed. It was the researcher's opinion that this would provide the most significant evidence of any association between EDB exposure and increased morbidity.

The investigators determined that among the workers who died, the incidence of deaths due to all causes as well as heart disease, cardiovascular disease and cancer of various sites was in most cases lower than the control group (45-64 years of age), or approximately the same as the control group. The author attributed this lower death rate to the preselection of healthy workers prior to employment. The authors concluded that, "it is difficult to conclude from the data on this relatively small group of persons who have had regular slight exposure to dibromoethane that there is any association between such exposure and any particular disease."

The Agency agrees with the investigators, and also finds that it is difficult to conclude that there is no EDB exposure-related cancer death in the workers. (Mishra, 1978a)

(4) Conclusions-Human Oncogenicity of EDB

Based on the evaluation of the rebuttals discussed above, the Agency concludes that, because no respondent has sustained the affirmative burden of proof set forth in 40 CFR 162.11(a)(4), the presumption of oncogenic risk to humans has not been rebutted. The Agency concluded that the latter two studies conducted in England are not useful in evaluating the human health risk of exposure to EDB. The Agency (CAG, 1978) considers only the first study listed above as technically acceptable. Though it did not show a statistically significant cancer incidence in exposed workers, the Agency concludes that the animal data provide substantial evidence that EDB is a likely carcinogen for humans.

2. Mutagenicity

In PD-1 the Agency evaluated all of the available studies on the mutagenic potency of EDB. These studies, summarized in Table 4, tested EDB for three types of mutagenic effects: point (gene) mutations, chromosomal aberrations and primary DNA damage. Each of these categories was further subdivided into positive or negative mutagenic effects. These are the conclusions reported in the PD-1:

> "In a memorandum dated 9-10-77, Dr. R. Pertel stated that there is ample evidence to fulfill both the multitest criteria for EDB as a mutagen as well as the scientific criteria of EPA's Science Advisory Board's (SAB) study group on mutagenicity. This evidence shows EDB to be positive in both prokaryotic (microbial) and eukaryotic (higher forms including mammals) for point (gene) mutational effects, with and without mammalian metabolic activation." (December 14, 1977; 42 FR 240, page 63141)."

40 CFR 162.11(a)(3)(ii)(A) states that a "... rebuttable presumption shall arise if a pesticide's ingredient(s)... induces mutagenic effects as determined by multitest evidence." Further, Section 162.3(4) defines the term mutagenic as "... the property of a substance or mixture of substances to induce changes in the genetic complement of either somatic or germinal tissue in subsequent generations." Based on the induction of point mutations by EDB in several tests, the Agency concluded that the mutagenic risk "... index has been exceeded by all registrations and applications for registration of pesticide products containing EDB, and that a rebuttable presumption against new or continued registration of such products has therefore arisen." (December 14, 1977, 40 FR 240, page 63135).

a. Mutagenicity Rebuttals

Four respondents submitted rebuttals specific to this presumption of the mutagenic risk of EDB (rebuttal nos. 3c,47,48,64). Rebuttal comments included general arguments about the mutagenicity testing systems used and specific statements about the studies reviewed in PD-1. These rebuttals, together with the Agency's scientific review and evaluation, are summarized and responded to in this section. Mutagenic studies on EDB which have become available since the EDB PD-1 was issued are also evaluated.

(1) General Comments

The rebuttals which relate to the mutagenicity RPAR express four general areas of concern: the significance of the testing systems; the limitations of the tests on EDB; available information; and the validity of specific studies.

(a) Significance of Mutagenicity Tests

The Great Lakes Chemical Corporation (Rebuttal No. 3C) and the Hopes Company (Rebuttal No. 64) questioned whether *in vitro* (or "test tube") tests indicate a potential for *in vivo* mutagenicity or carcinogencity:

"While EDB has produced some mutations in *in vitro* testing, the significance of these results in assessing the mutagenic or carcinogenic risks of EDB is not established and subject to serious scientific debate." (Rebuttal No. 3C).

Ethyl Corporation (Rebuttal No. 48) also questioned the predictive utility of existing test systems. They mentioned microbial, insect, and cell culture studies which require extrapolation of results to apply to humans: "...The ability of EDB to induce mutations in a variety of test systems is only suggestive of its potential to induce mutations in the human population..." and "...there is no evidence to determine the relative risk..." (Rebuttal No. 48).

In response, the Agency supports the mutagenicity studies of non-human test systems. Data from non-mammalian test systems are relevant in considering the potential mutagenicity of a compound. In the absence of adequate mammalian systems which are sensitive enough to exhibit the many mechanisms of possible genetic damage in reproductive cells, other test systems are utilized to expose the chemical's intrinsic capacities to alter genetic components. This evidence has generated a presumption of hazard as stated in the PD-1.

Table 4 Summary of Mutagenicity Testing of EDB

Genetic Event and Test System	Species/Strain/Type	Concentration or Dose	Genetic Indicator or Effect	Result	References
Gene (Point) Mutation					
Bacterial, In vitro	Salmonella typhimurium his G 46 TA 1530, 1535, 100	10-10,000 ug (10 ul)/ plate	Reversions by Base-Pair Substition	Positive w/o MA[1/]	(Brem, et. al, 1974) (Buselmaier, et al, 1972) (McCann, et al. 1975)
Bacterial, Host-Mediated Assay (mouse)	S.typhimurium G 46/his	500 mg/kg i.m. to mouse	Reversions	Positive	(Buselmaier, et.al, 1972)
Eukaryotic Microbial, in vitro	Neurospora crassa ad -3	1.2-1.63 ul/ml	Recessive Lethals	Positive w/o MA	(De Serres, at al, 1970) (Malling, 1969)
Insect, In vitro	Drosophila melanogaster males	0.3 mM fed ad. lib. 3 days	Sex-linked Recessive Lethals	Positive	(Vogel, et al, 1974) (early germ cells affected)
Somatic Cell Culture in vitro	Mouse Lymphoma cells L5178y TK Heterozygotes	1.0-3.0 mM for 2, hours	Induction of TK Homozygotes	Positive (dose response)	(Clive, 1973)
Higher Plants	Tradescantia, Mutable Clones	3.6 - 222.9 ppm (gas)	Stamen Hair Color (blue to pink)	Positive (dose response)	(Nauman, et al 1974;;Sparrow et al.)
Higher Plants	Barley Seeds	0.1-1.1 mM	Chlorophyll Mutations	Positive at LD_{50}	(Ehrengerg, et al., 1974)
Bacterial, In vitro	S. typhimurium his G 46 TA 1538	11.5 uM 19 ul/plate	Reversions by Frame-Shift	Negative w/o MA	(Brem, et al, 1974)
Bacterial, In vitro	S. typhimurium LT 2 gal-chl A	5 ul/plate	Deletions	Negative w/o MA	(Alper, et al, 1975)
Bacterial, Host-Mediated Assay (mouse)	S. marcescens A 21/leu	500 mg/kg i.m. to mouse	Reversions	Negative	(Buselmaier, et al., 1972)

1/ w/o MA= without metabolic activation

Experimental animals are utilized throughout the various disciplines of toxicology to predict adverse effects and the probability of inducing certain effects in humans for a given range of doses of a compound. Certainly there exist numerous examples of cases where humans did not display the anticipated effect predicted from animal studies. Humans have also shown effects not demonstrated in the experimental studies, or have been more or less susceptible than the non-human species. However, the theorum that "the basic biological mechanism explored and documented in experimental studies with non-human subjects is valid when extrapolated to humans to predict risk," still holds firmly, as evidenced by the universal acceptance of non-human experimentation in science. (Chaisson, 1978)

Predicting potential of a compound to induce mutagenic effects in humans is more difficult than predicting other types of toxicities, but the logic can still be founded on establishing the mechanism in appropriate non-human species. This concept is discussed at length in the DHEW document by the Subcommittee on Environmental Mutagenesis, 1977. Valid studies demonstrating mutagenic effects in experimental animals, and the mechanisms of those effects, coupled with serious consideration of pharmacologic principles and biodistribution in humans do establish the framework for presuming a mutagenic hazard to humans. The evidence of mutagenic potential in non-human species can be used to predict potential for humans.

The application of test results was addressed by the Great Lakes Chemical Company: "...None of the test systems used were capable of detecting anything other than short-term effects of a mutagen. The same applies to the evaluation of the genetic risk." (Rebuttal No. 3C).

The philosophy summarized above has been considered by EPA and is addressed in the document by the DHEW Committee to Coordinate Toxicology and Related Programs, 1977. The problems in definitively identifying human mutagens are recognized. However, interpretation of the available test results with the pharmacokinetic and biochemical considerations, and matching of results of reproductive studies can give presumptive evidence on which hazard to humans can be predicted and regulatory decisions contemplated (Chaisson, 1978).

Great Lakes Chemical Co. expressed a related point: "Even an established human mutagen is not likely to have any mutagenic effect unless the exposure reaches the testes or ovaries." (Rebuttal No. 3C).

The Agency agrees completely with this statement. It is obvious that in order to have a heritable effect, the mutagen must reach the reproductive tissue. As discussed in the next section, the available reproductive studies provide evidence that the reproductive tissues in exposed animals can be adversely affected by EDB.

(b) Limitations of Available Tests

Hopes Company states that there is a necessity for a multitest approach to mutagenicity testing, with strong emphasis on those tests which relate directly to man, and that the only real way to test for heritable mutation in man is to utilize a test system with guidelines from the DHEW document "Approaches to Determining the Mutagenic Properties of Chemicals: Risk to Future Generations." The Agency agrees with the principle set forth in this document that a multiple-system approach is necessary since no single adequate test exists. Hopes Company has outlined the optimal criteria, but has failed to cite what the species and test protocol would be. The Agency recognizes the shortcomings of each test system but also the utility of the tests when they are considered as a group.

(c) Validity of Specific Studies

The Douglas Chemical Company criticized the Buselmaier, 1972 study: "Response data indicated the data presented are insufficient for evaluating the effect of EDB in the host-mediated assay with S. marcescens, since results of only a single dose were reported." (Rebuttal No. 47).

The Agency agrees that an ideal protocol in the host-mediated test would include at least three dosage levels, with at least ten animals per dose level. Utilization of a different protocol tempers the resulting strength of conclusions, but does not nullify the fact that the 500 mg/kg dose (subcutaneous) increased the mutation frequency over the control group by a factor greater than eight.

The rebuttor also rejected the use of the inconclusive results of Epstein et al., 1972, to support the RPAR. The rebuttor's reasons for this position were unclear. The Agency did not use this study to support the presumption of hazard; the study was mentioned to establish that it was considered, but that the results were inconclusive.

In addition, the rebuttor disagreed with EPA's rejection of the results ofBrem, (1974) and implied that the single dose used in the study was evidence of no mutagenic potential. The rebuttor's position is not adequately developed. EPA has considered this study to be invalid because no information on the effective dose or range is given. Also, the strain used, S.typhimurium TA 1538, would not be expected to predict activity since this strain is designed to detect frameshift mutagens and EDB is more likely to cause base-pair substitution mutations. The rebuttor's position does not rebut the RPAR presumption.

b. Agency Position on Mutagenicity Rebuttals

The Agency has reached the following general conclusion on all the rebuttals submitted in argument against the Agency's position in PD-1:

"The methodology currently used in mutagenesis assay studies has been generally accepted on theoretical grounds and offers the only means to predict adverse genetic effects in humans." [and] "The comments in the Rebuttal Nos. 3C, 47, 48 and 64 underscore the limitations of these test systems but do not rebut the Agency's presumption of hazard as outlined in the RPAR document." (Chaisson, 1978).

Thus, the Agency concludes that the mutagenic risk as stated in the RPAR Notice has not been rebutted, since no respondent to that Notice has sustained the affirmative burden of proof set forth in 40 CFR 162.11 (a)(4).

c. Re-evaluation of Mutagenicity Data and Review of New Studies

In the light of recent research, the Agency has re-evaluated the mutagenicity data presented in the RPAR Notice and reviewed additional studies as to the mutagenic potential of EDB.

In the PD-1 the Agency concluded that "no positive chromosomal damage studies have been found for EDB." After a review of the study by Ehrenberg, *et al* ., (1979), the Agency (Mauer, 1979) has concluded that, in addition to the point (gene) mutations cited in the PD-1, this study also demonstrates that EDB causes chromosome-damaging effects as discussed below.

EDB was shown to cause chromosome exchange in barley seeds which were treated with 1.4 mM of EDB for 24 hrs. Cells were analyzed for chromosomal aberrations in the first mitosis following treatment. The observed frequencies of induced chromosomal aberrations were determined to be significantly higher than the control material.

Additional studies, not available at the time of the RPAR Notice, have since been reviewed by the Agency (Mauer, 1979). These studies lend additional support to the Agency's position that there is multitest evidence indicating that EDB induces mutagenic effects in laboratory test systems. The studies cited below all show positive effects. They are discussed according to the specific genetic indicator involved, i.e.: (1) point (gene) mutation; (2) chromosomal aberration; (3) primary DNA damage.

(1) Point (gene) mutation

EDB at concentrations as low as 0.2 parts per million has been shown to induce sex-linked recessive lethal mutations in *Drosophila melanogaster* (Kale and Baum, 1978). Early germinal stages were affected at a rate 3 times as great as the spontaneous mutation rate, indicating that even lower concentrations could cause mutagenic effects.

EDB has also been shown to cause reverse mutations in *Aspergillus nidulans* and *Escherichia coli* as well as induction of ochre suppressors in *E.coli* (Scott, B.R., *et al* , 1978). The potency of EDB was shown to increase with metabolic activation by a plant extract of *Tradescantia* clone 4430.

(2) Chromosomal damage

EDB produced micronuclei in tetrads of microsporogenesis of *Tradescantia* clone 4430 by a 6-hour treatment with 20-160 ppm of EDB gas (Ma, et al., 1978). A range of 0.001-0.002 micronuclei/tetrad/ppm-hr. was established by dose-effect experiments.

(3) Primary DNA damage

EDB was shown to indirectly interact with nucleophilic sites and strongly inhibit RNA transfectivity via the production of "half-mustards" (Kondorosi, et al., 1973). Q -RNA was inactivated by EDB in the presence of thioglycol after treatment for 1 hr. in a phosphate buffer.

These recent studies, not available at the time PD-1 was issued, reaffirm the results of earlier citations and indicate that in addition to causing point (gene) mutations and primary DNA damage, EDB possesses chromosome-damaging effects as evidenced by several in vitro assays.

An additional study investigating the potential mutagenicity of EDB in the rat and mouse has been reviewed by the Agency. The study, an investigation of dominant lethal mutations, concluded that EDB at a dosage of 10 or 30 mg/kg in mice and 100 or 150 mg/kg in rats did not induce dominant lethal mutations in either of the species (Teramoto, et al., 1980).

It is the Agency's position (Mauer, 1979) that the negative results of this test are no indication of other genetic events which can occur as a result of the transport of EDB or its metabolites to mammalian germ cells. The genetic end-point of this test is gross chromosomal damage, a relatively insensitive and limited indicator of total genetic damage. This test does not detect the variety of genetic damage demonstrated in the other test systems reviewed by the Agency. Thus, the Agency concludes that this study is of very limited significance as compared to positive mutagenicity assays on EDB in multiple test systems.

d. Conclusions

Based on the evaluation of the rebuttals and new studies discussed above, the Agency concludes that no respondent has sustained the affirmative burden of proof set forth in 40 CFR 162.11(a)(4), and that the presumption of mutagenic risk to humans from EDB has not been rebutted. The Agency (Mauer, 1979) states:

> "Sufficient evidence exists to indicate EDB presents a potential mutagenic risk for humans, especially for individuals exposed to the relatively high levels of the chemical measured in occupational settings, such as during soil application and commodity fumigation. In summary, the evidence is as follows:
>
> o EDB is a potent mutagen, producing a broad spectrum of mutational events in submammalian in vitro systems, higher plant, and mammalian cell cultures.
>
> o EDB is mutagenic to germ cells in vivo, as shown by the sex-linked recessive lethal test in *Drosophila*, including significant increases in lethals in a dose-dependent fashion.
>
> o Notwithstanding the removal of a major portion of EDB administered experimentally to mammals, EDB is transported to mammalian germ tissues in amounts sufficient to produce significant effects as indicated by spermatogenic effects in bulls and rats. In addition, tissue distribution studies show measureable [sic] amounts can be transported to testicular tissue which may result in an accumulation of genetic lesions induced by this bifunctional alkylating agent. "(Mauer, 1979).

In regard to the suitability of the data to support a quantitative estimate of mutagenic risk, the Agency asserts:

> "Although there is a strong indication of risk at current levels of occupational exposures, the present data base does not permit quantification of mutagenic risks from the levels of EDB exposure likely to be encountered by the general population. As discussed by an EPA consultant...no coherent body of relevant data is available which could either be used to relate human EDB exposure _directly_ to mutagenic events in any mammalian test system, or from which dose-response relationships can be extrapolated to humans. Further, previous indirect attempts to quantify risk from mutagenic studies in _Drosophila_ did not take into account differences in mutational responses between ionizing radiation and many chemical mutagens... Also, there are basic differences in transport mechanisms between mammals and _Drosphila_ which can affect the pharmacokinetic disposition of chemicals, especially via the inhalation route of exposure.
>
> Experimental work is currently in progress for estimating the mutagenic risk of EDB... patterned after studies already published on EMS... This approach will attempt to overcome the previous shortcomings of quantitative risk estimation mentioned above by utilizing a common unit of 'dose' to the germ lines of both _Drosophila_ and male mice exposed to radioactive-labeled EDB. This 'dose' is defined as the amount of chemical bound to germinal DNA and is measured as the number of alkylations per DNA-nucleotide. The 'dose'-mutation curve in _Drosophila_ will be compared to the exposure-'dose' curve in the mouse. In this way it may be possible to derive a quantitative estimate of the genetic hazard to humans from a given concentration or exposure level of EDB, since one could estimate the dose (as alkylations) to mammalian germ cells from given body exposures, and the genetic consequence of that dose in the _Drosophila_ test." (Mauer, 1979).

3. _Reproductive Effects_

In Position Document 1 (PD-1), the Agency cited several studies in bulls and rodents which established that EDB could adversely affect mammalian reproductive development by interfering with the production of male gametes and the development of embryos. Adverse effects in hen egg production were also noted. In summary, the animal studies reported the following effects:

> _Bulls_ - reduced sperm production; reduced sperm motility; and abnormal sperm structure. (Amir, 1973; Amir and Lavon, 1976; Amir and Ben-David, 1973)
>
> _Rats and mice_ - selectively damaged spermatogenic cells resulting in "transient" sterility; decreased fetal implants and fetal weight. (Edwards _et al._, 1970; Short _et al._, 1976)
>
> _Chicken Egg Production_ - reduced egg weight; reduced egg production; reduced fertility; generalized reduction in the permeability of ovarian membranes. (See Table 9, of PD-1)

An Agency Working Group concluded that the reproductive effects studies met the RPAR risk criterion stated in 40 CFR 162.11 (a)(3)(ii)(B), that a rebuttable presumption shall arise if a pesticide "produces any other chronic or delayed toxic effect in test animals at any dosage...which is substantially higher than that which humans can reasonably be anticipated to be exposed." The Working Group also concluded that, because sufficient data did not exist for determining a no observable effect level for EDB via oral, inhalation or dermal routes of exposures, acceptable levels of exposure could not be calculated for persons exposed by any of these routes following the pesticidal uses of EDB.

Based on the above evidence, the Agency adopted the following position in the PD-1:

> "On the basis of scientific studies and information summarized in the Position Document [(1)], the Agency has concluded that the risk index for reproductive effects has been exceeded by all registrations and applications for registration of pesticide products containing EDB and that a rebuttable presumption against new or continued registration of such products has therefore arisen."

Four rebuttals (Rebuttal nos. 3C, 48, 64, and 79) were submitted in response to the reproductive RPAR. The Agency has divided these into two broad groups: those which addressed uncertainties in extrapolating to man from the positive animal laboratory studies; and those studies which investigated the health of workers occupationally exposed to EDB.

a. Response to Rebuttals of Extrapolating from Animal Reproductive Disorder to Humans

No rebuttals seriously questioned the validity of the animal reproductive studies evaluated in the PD-1. However, all respondents noted the reversibility of the effects at all but the highest doses in hens and the general reversibility of effects in bulls following cessation of dosing. Respondents argued the effects produced in hens are probably specific to the hens and that the bull is specifically sensitive to EDB.

Generally, the rebuttals disputed the significance which the Agency placed on the animal studies in the PD-1. More specifically, the rebuttals argued that the reproductive disorders observed in bulls orally administered EDB cannot be used to determine a safe level of human exposure to inhaled EDB. The basis for this argument was that the bull is unusually sensitive to EDB. In addition, the rebuttals contended that it is inappropriate to determine a margin of safety by comparing levels to which humans are exposed via inhalation with the amount of EDB to which bulls were exposed orally.

The Agency concludes these rebuttals are not valid and do not change the Agency's position. In the absence of adequate human data, the Agency's normal policy is to use data from the most sensitive species which in this case is the bull. This procedure is dictated by regulatory prudence; in the absence of adequate human data it is reasonable to assume that man is at least as sensitive as the most sensitive species for which data are available. The question of assuming that all EDB inhaled is retained is basically similar to the question of the most sensitive species: in the absence of adequate data it is prudent to assume that the worst case applies (e.g., all inhaled EDB is retained). Thus, the Agency concludes that it is in the interest of public health to use the results from the reproductive studies on bulls to evaluate the reproductive risks to humans. In further support of this assumption, the

Agency has recently completed an inhalation study on rats (discussed later in this section) which demonstrates that this exposure route also causes deleterious effects upon the reproductive organs.

b. Response to Rebuttals Addressing Human Studies

In response to the reproductive RPAR in the PD-1, two epidemiology studies were submitted (Rebuttal no. 48). At the same time the Agency conducted its own study (Griffith, et al, 1978).

The first study submitted in rebuttal was a retrospective study of inferred fertility of married men occupationally exposed to EDB (Wong, 1977). Basic marital reproductive histories were collected from five groups of male workers - one group from each of four EDB manufacturing plants in the U.S. and a fifth group from a plant in Great Britain. For each of these groups, expected and observed births were compared for the families of workers exposed to EDB. Basically it was the conclusion from each of these "mini" studies that expected and observed human fertility were essentially the same and thus there was no evidence that EDB had an effect upon human fertility.

The Agency concludes that this study is of limited value in evaluating the human reproductive hazards of EDB. The Agency bases its rejection on numerous inherent weaknesses in the study and the general fact that negative fertility studies such as these are a very insensitive measure of the possible reproductive hazards of EDB. Two of the deficiencies in these studies, which were also noted by the author, included: 1) none of the U.S. groups had matching controls; and, 2) the data for the U.S. groups were compared to fertility data published by the National Center for Health Statistics which included non-married women, while the plant data did not, thus tending to artificially inflate the plant rates.

The second rebuttal study (Ter Haar, 1978) presented summary results of a sperm count survey of 59 employees of an EDB manufacturing plant at Magnolia, Arkansas. (This study was also referred to in rebuttal number 3C.). Workers were divided into two groups: those exposed to air levels of less than 0.5 ppm EDB and those exposed to levels between 0.5 - 5.0 ppm.

The Agency concludes that this study is of limited value in evaluating the possible reproductive hazards of EDB. In general, the Agency considers sperm count studies such as this one, which are negative, to be insensitive measuresof the possible human reproductive hazards of a substance. Reproduction is comprised of numerous facets, only one of which is the sperm count in males. Other parameters in males, including the number of abnormal sperm cells, motility of cells, and ultimately male fertility, can be affected. In addition, the potential effects on female reproduction must also be examined, even if a substance has been demonstrated to have no apparent effects on male reproduction. However, human sperm count studies which are postive and were conducted according to scientifically accepted protocols, do provide adequate evidence to demonstrate that a substance possesses risks of disorders to human reproduction. In addition to these general considerations, this particular study has specific technical flaws, including: 1) the failure to document or substantiate the finding of correlation between sperm count and exposure index; and 2) the failure to provide documentation on how workers were chosen for the study, the percentage of all exposed individuals included in the study, and the individual exposure estimates.

c. Recent Agency Sponsored Study

The Agency study (Griffith, et al., 1978) was undertaken to provide additional information on potential health effects of agricultural uses of EDB, with particular focus on reproductive effects. Semen samples were obtained from a total of forty-four individuals in four cohorts: (1) citrus fumigators at two locations in Florida; (2) rice fumigators in Texas; (3) citrus fumigators in Texas; and (4) a mixed group of carrot farmers and researchers in New Jersey. Semen samples were immediately analyzed for volume, sperm density, and motility. In addition, blood samples were drawn from all participants and tested for blood chemistries, testosterone levels, certain hormones and organochlorine residues (only for the Florida and Texas cohorts).

Air monitoring for EDB was conducted on a very limited basis. The number of data points were inadequate for use in standard statistical analyses to determine if EDB had a discernable effect on observed sperm measures. Initially, lifetime days of use and use-index (average pounds per day of use) were multiplied together and used as a surrogate measure of potential exposure to determine if an inverse relationship existed with the measured sperm counts. This surrogate was used because the Agency had very little data on the exposure to EDB of users. The Agency has since concluded however, that this surrogate exposure is an invalid measure of potential exposures to EDB. Recent monitoring studies demonstrate that citrus fumigators have significantly higher EDB exposures (on a yearly basis) than any other group of EDB users, and yet, this is one of the smallest volume uses of EDB. In contrast, soil fumigators use considerably more EDB, but are exposed to considerably lower levels of EDB than the citrus fumigators, because they soil-injected EDB outdoors using tractor-drawn chisels. Thus, this surrogate use index (days x lbs. applied per day) was a very inaccurate measure of the actual exposure to EDB for each cohort.

The Agency has summarized the sperm counts of the cohorts from this study in Table 5. In addition, in Table 6, the Agency has summarized results fromstudies conducted by McCloud which investigated sperm counts for males from"fertile marriages" and from "infertile marriages".

The Agency is reexamining the results from its study, but recognizes that the study will have very limited value to assessing the reproductive hazards of exposures to EDB. The study consisted of a very small number of individuals (a total of forty-four) and a much smaller numbers of individuals within each of the 4 cohorts. Standard statistical test results which take into account age and sex consist of such small sample sizes, would be of limited reliability.

d. Recent Agency Animal Study

The Agency has sponsored a study in which certain reproductive parameters were measured in rats exposed to EDB via inhalation (Short et al., 1978). While a variety of reproductive effects were noted in this study, the most noticable effect was atrophy of the prostate as illustrated in Table 7 below.

TABLE 5

SPERM COUNT DISTRIBUTIONS BY COHORT AND OCCUPATION

Cohort		Median Count	Frequency Distribution (%) of Counts (10^6ml) by Cohorts						%Counts
State	Occupation	(x 10^6/ml)	≤ 10	10.1-20	20.1-40	40.1-60	60.1-100	>100	≤ 20 (10^6/ml)
Florida	Citrus Fumigators (N=14)	53.5	14.3	7.1	14.3	21.4	7.1	35.7	21.4
Texas	Citrus Fumigators (N=17)	59.5	5.9	0	23.5	23.5	17.6	29.4	5.9
Texas	Rice Fumigators (N=8)	76.4	0	0	0	12.5	50.0	37.5	0
New Jersey	Carrot Farmers & Researchers (N=5)	123.0	0	0	0	0	20.0	80.0	0

TABLE 6

SPERM COUNT DISTRIBUTIONS FOR MALES FROM INFERTILE AND FERTILE MARRIAGES

		Median Count (10^6/ml)	Frequency Distribution (%) of Counts (10^6ml) by Cohorts						%Counts
			≤ 10	10.1-20	20.1-40	40.1-60	60.1-100	>100	≤ 20 (10^6/ml)
Macleod 1977*	(N=9,000)	74	8.9	6.1	11.4	11.8	25.3	36.5	15.0
Macleod 1951**	(N=1,000)	90		(20=5%)+	12	12	27	44	5

*Males from infertile marriages
**Males from fertile marriages
+ Categories <10 and 10.1-20 combined

Table 7

Lesions in Reproductive Organs of Male Rats Exposed to EDB

For 10 Weeks and Sacrificed at the End of Exposure

	EDB (ppm)*/			
Lesion	0	19	39	88
Testis				
Atrophy (Severe)	0/10[a]	0/10	0/10	6/6
Calcification	0/10	1/10	0/10	2/6
Epididymis				
Atrophy (Moderate to Severe)	0/10	0/9	0/10	6/6
Prostate				
Atrophy (Moderate to Severe)	0/10	0/10	10/10	6/6
Prostatitis	0/10	0/10	0/10	1/6
Seminal Vesicles				
Atrophy (Moderate to Severe)	0/10	0/10	0/10	6/6

---

* ppm in inspired air.

[a] Number of rats affected/number of rats inspected.

The results of this study suggest that the prostate is the most sensitive tissue. Thus, while the testis, epididymis, prostate and seminal vesicles are markedly atrophied in the presence of 88 ppm EDB, only the prostate is affected at 39 ppm. Based on this study, the NOEL for atrophy of the prostate is 19 ppm (146.11 mg/m^3) in the rat.

e. Conclusions on the Reproductive Effects RPAR

The Agency has examined the rebuttals submitted and other pertinent data and has concluded that the presumption of reproductive disorders as stated in the RPAR notice has not been rebutted because no respondent to that notice has sustained the affirmative burden of proof set forth in 40 CFR 162.11(a)(4). While there are no reliable human data available to help assess the human reproductive effects of EDB, the available animal data clearly indicate that EDB causes adverse reproductive effects in the bull, rat and hen. The inhalation NOEL for EDB in the rat is 19 ppm (146.11 mg/mg^3) based on atrophy of the prostate. Based on this NOEL and the exposure levels discussed in the next section, the Agency concludes that (as was originally stated in PD-1 with respect to the bull) there is not an ample margin of safety from adverse reproductive effects for humans exposed as a result of the current pesticidal use practices of EDB.

B. Human Exposure To EDB From Pesticidal Uses

Human exposures to EDB from pesticidal uses occur through three exposure routes: dietary, inhalation by evaporation of pesticides containing EDB, and dermal by contact with these pesticides.

1. Dietary Exposures

Residues of EDB may enter the human diet as a result of the following registered uses:

- preplant soil fumigation of agricultural commodities and the possibility of groundwater, and, ultimately, drinking water contamination resulting from this use;
- post-harvest fumigation of stored grains and grain products;
- fumigation of grain mills, mill machinery, and handling equipment (including transportation equipment);
- post-harvest fumigation of fruits, nuts or vegetables for quarantine purposes;
- possibly through control of wax moths in beehives and associated equipment.

In the next five sections, dietary exposure levels resulting from each of these registered uses are examined. These data are taken from two major investigations on EDB residues occurring in the human diet: "Dietary Burden of Ethylene Dibromide Used as Soil, Grain, Grain Machinery, and Fruit Fumigant" (Holder, 1979), and "Final Dietary Exposure Analysis for Ethylene Dibromide Resulting from Residues in Fumigated Crops and Food Commodities" (Worthington, 1978).

a. Residues From Preplant Soil Fumigation

The Agency has examined the four known studies which investigated EDB residues in crops grown in EDB-fumigated soil. These include the following:

- An unpublished series of reports to the Great Lakes Chemical Corp. from Litton Bionetics, Inc. (Rebuttal No. 3C);
- An unpublished report from the Ministry of Agriculture and Forestry of Japan (Kenichi, 1978);
- Data compiled by the Food and Drug Administration, DHEW, from their Compliance Program for DBCP and EDB;
- A report by the California Department of Food and Agriculture (CDFA) analyzed 29 samples of nine crops grown in EDB-fumigated soils in California, with a stated level of detection of 1 part per billion (Maddy, 1979a).

Taken collectively, these studies indicate that residues of EDB in crops grown in EDB-fumigated soils are, if they occur, below the level of instrument detection. However, the Agency cannot be certain that residues will not occur. Each of these studies has been carefully reviewed by Agency scientists and each was found to have some deficiencies which precluded the Agency from categorically accepting their findings. The studies from both Litton Bionetics and Japan's Ministry of Agriculture and Forestry used analytical procedures which were only sensitive to 0.01 ppm and involved application rates of EDB which were generally less than standard rates. The FDA study involved analysis of foods obtained from retail groceries with no knowledge that EDB was even applied to the soil in which these crops were grown. In addition the analytical method was only sensitive to 0.01 ppm. The CDFA study (Maddy, 1979a) is probably the most convincing of all the studies to date. The level of detection is stated to be 0.001 ppm. However, because the analytical method used was not validated by CDFA through mass spectrophotometry, these data must be considered as preliminary.

The fact, that residues of the chemically related pesticide DBCP (in the .001-.01 ppm range) have been found in crops treated by similar use patterns, augments the concern that residues of EDB may occur. Therefore, in view of these findings, the Agency assumes that treated crops can bear EDB residues up to the limit of detection, which the Agency considers to be 0.001 ppm.

Using the 0.001 ppm residue limit, the Agency has calculated the potential body burden which may result from soil fumigation uses (Table 8). The body burden is calculated in mg EDB/kg body weight/day, assuming a 1,500 g diet and a body weight of 60 kg. The 60 kg body weight value is considered to be the average for an individual from a family of four. The food factors (the average percentage of the human diet) listed are the values reported in the update of the Food Factor Tables (Schmitt, 1978). The percentages of crops currently treated are documented by L. Zygadlo (1978) and the USDA/State/EPA Assessment Report (1978). The values for the estimated percentage of crops treated with EDB, if all DBCP uses are cancelled, are based on the portion of DBCP uses for which EDB is an alternative pesticide. The calculated dietary burden (DB) per day per person is derived from the calculation:

$$\text{DB(mg/kg/day)} = \text{ppm Residue} \times \frac{\text{\% of the Human Diet}}{100} \times$$

$$\frac{\text{kg Diet}}{\text{kg Body Wt}} \times \frac{\text{\% Crop Treated}}{100}$$

As indicated in Table 8, the estimated average daily intake of EDB from residues in crops at current use levels is 2.59×10^{-7} mg/kg per day. If it is assumed that 100% of the crops bear EDB residues, the estimated dietary burden (DB) is 4.1×10^{-6} mg/kg per day. This latter figure is appropriate if an individual eats 100% treated crops.

Site preparation for fruit tree planting, an additional registered preplant use of EDB, is not listed in Table 8. This is because no detectable residues have been found in the fruits, and also because the Agency believes that it is extremely unlikely that this fruit would contain residues, due to the high volatility of EDB coupled with the many years between EDB application and first fruit harvest.

b. Postharvest Fumigation of Stored Grains

Grains are usually treated post-harvest to prevent insect infestation. Liquid mixtures of organic solvents such as carbon tetrachloride (CT), ethylene dichloride (EDC), and/or carbon disulfide (CS_2) are commonly used for this purpose. EDB generally constitutes inthe range of 1% to 9% of the weight of the liquid mixture. A mixture of chemicals is used because EDB alone would not penetrate sufficiently to the bottom of the storage bin. CT is an effective

Table 8

Calculated dietary burden (DB) of EDB residues in the human diet resulting from the soil fumigation uses.[1]

Crop	Crop Tolerances of Inorganic Bromide from Soil Incorporation (ppm)	Maximum Expected Residue of EDB (ppm)	% of diet made up of Currently Treated Crops	Food Factor of diet	DB if all of Crop Consumed Bears Residue (mg/kg/day)	Estimated EDB at Current Use Level (mg/kg/day)
Asparagus	10	0.001	NEGL	0.14	3.50×10^{-8}	0
Broccoli	75	0.001	9.5	0.10	2.50×10^{-8}	2.38×10^{-9}
Carrots	75	0.001	21.0	0.48	1.20×10^{-7}	2.52×10^{-8}
Cauliflower	10	0.001	3.2	0.07	1.75×10^{-8}	5.60×10^{-10}
Corn, sweet	50	0.001	NEGL	1.43	3.58×10^{-7}	0
Cotton	25	0.001	0.2	0.15	3.75×10^{-8}	7.50×10^{-11}
Cucumbers	30	0.001	28.0	0.71	1.78×10^{-7}	4.97×10^{-8}
Eggplant	50	0.001	1.4	0.03	7.50×10^{-9}	1.05×10^{-10}
Lettuce	30	0.001	0.2	1.31	3.28×10^{-10}	6.55×10^{-10}
Lima Beans	5	0.001	45.0	0.19	4.75×10^{-8}	2.14×10^{-8}
Melons	75	0.001	11.0	2.00	5.00×10^{-7}	5.50×10^{-8}
Okra	50	0.001	71.0	0.07	1.75×10^{-8}	1.24×10^{-8}
Parsnips	75	0.001	NEGL	0.03	7.5×10^{-9}	0
Peanuts	25	0.001	0.1	0.36	9.00×10^{-8}	9.00×10^{-11}
Peppers	30	0.001	NEGL	0.12	3.00×10^{-8}	0
Pineapple	40	0.001	27.0	0.30	7.5×10^{-8}	2.03×10^{-8}
Potatoes	75	0.001	1.1	5.43	1.36×10^{-6}	1.49×10^{-8}
Squash	50	0.001	NEGL	0.03	7.50×10^{-9}	0
Strawberries	5	0.001	4.4	0.18	4.50×10^{-8}	1.98×10^{-8}
Sweet Potatoes	50	0.001	5.4	0.40	1.00×10^{-7}	5.40×10^{-8}
Tomatoes	50	0.001	6.8	2.87	7.18 x 10-7	4.38 x 10-8
				Total	4.1×10^{-6}	2.59×10^{-7}

"carrier" and EDC is added to the mixture to create the proper vapor pressure. A typical example of a commodity fumigant is Dowfume EB-5, which contains CT, EDC, and EDB in 63:30:7 proportions.

The data available to the Agency demonstrating residues in EDB-treated grains are taken from a variety of published papers which report a wide range of EDB residue levels. This broad range results from numerous factors, including the type and condition of grain, construction variation in storage bins selected, EDB application methods and rates, aeration and sampling techniques, and other related factors. Table 9 summarizes the ranges reported in the available studies.

Table 9

EDB residues (ppm) Reported in Fumigated Grains *

Aeration Period (Weeks) after Fumigation

Grain	0	1	4	13
Wheat	12-1500	1-240	5-33	0.6-5.3
Corn	37-1565	21-61	2.5-581	0.3-3.5
Sorghum	<1-5.7	14-45	2.1-15	0.9-8.5
Barley		2.2-6.3	1.-2.2	0.9-1.9
Rye	20-32			
Oats		10 - 15 "several weeks after fumigation"		

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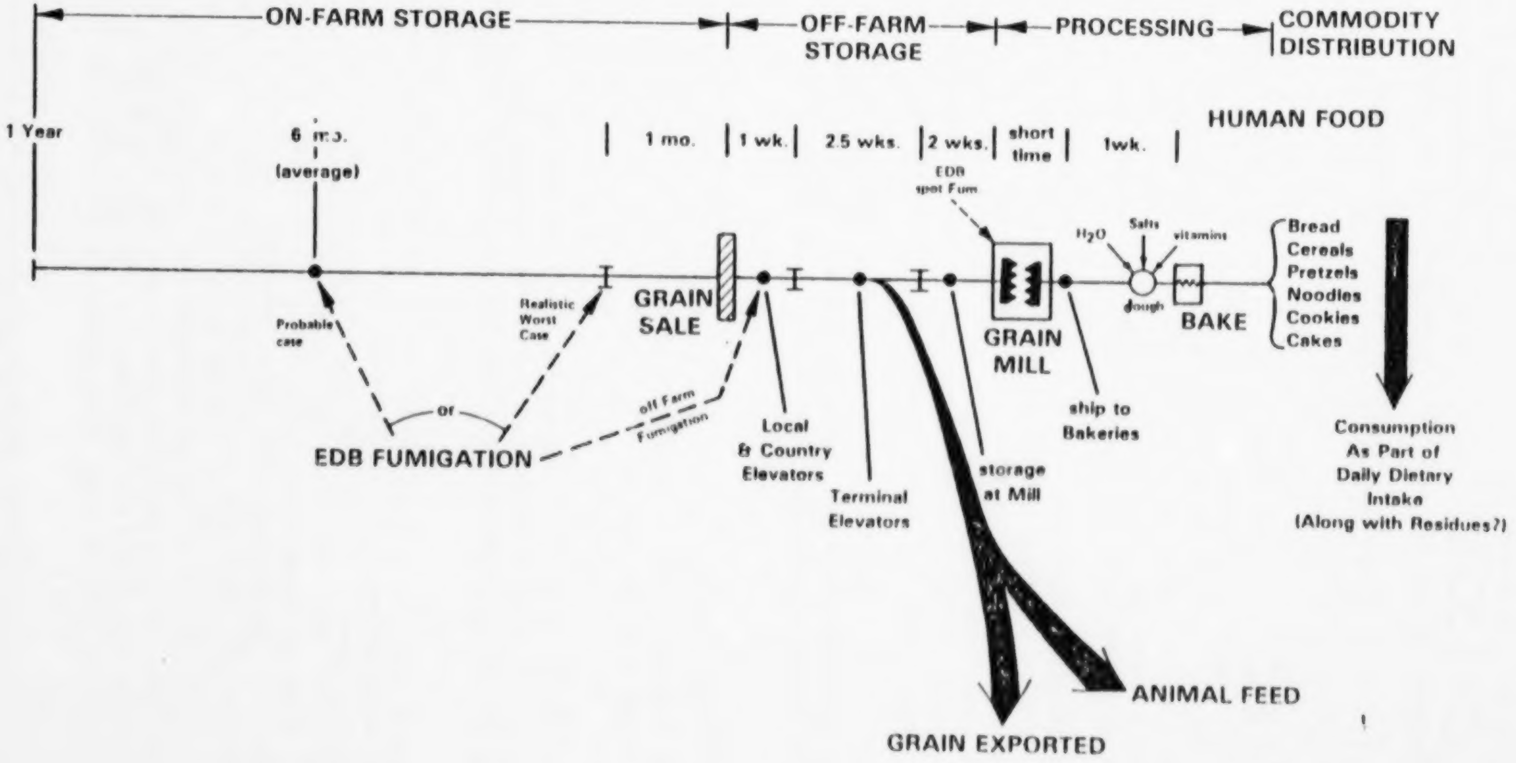
* (Worthington, 1978)

In spite of the wide variation in values reported, a consistent pattern of decline, which will be discussed later in the text, is apparent from the data presented in Table 9.

Of the grains for which EDB is registered as a fumigant, only wheat and rice make up appreciable portions of the human diet. Wheat forms by far the larger portion of the human diet than does rice: 10.36% for wheat and 0.55% for rice. Therefore, persistence of EDB in wheat is expected to have a much greater impact on the human diet (Holder, 1980). Accordingly, the Agency's analysis will focus on EDB residues in wheat, flour and bread.

It is important to note, however, that human dietary exposure can result from the use of EDB on other grains and rice. Corn oil, corn meal, corn cereals, other grains, and rice can contain residues of EDB as a result of the fumigation of stored corn, although most of the stored corn fumigated with EDB is used as livestock feed (DPRA, 1978). The Agency recognizes that these other uses could result in secondary contamination of the human diet through residues of EDB in meat, milk, rice and other products. However, the Agency has no data to support or dismiss this hypothesis, and therefore considers it to be a data

FIGURE I
TIME-LINE OF WHEAT AND WHEAT
BY-PRODUCT DISTRIBUTION WITH EXPECTED
TIMES FOR EDB FUMIGATION


ON-FARM STORAGE
OFF-FARM STORAGE
PROCESSING
COMMODITY DISTRIBUTION
1 Year
6 mo. (average)
1 mo.
1 wk.
2.5 wks.
2 wks.
short time
1wk.
HUMAN FOOD
EDB spot Fum
H_2O
Salts
vitamins
dough
Bread
Cereals
Pretzels
Noodles
Cookies
Cakes
Probable case
Realistic Worst Case
GRAIN SALE
GRAIN MILL
BAKE
or
EDB FUMIGATION
off Farm Fumigation
Local & Country Elevators
Terminal Elevators
storage at Mill
ship to Bakeries
Consumption As Part of Daily Dietary Intake (Along with Residues?)
ANIMAL FEED
GRAIN EXPORTED

gap. The presence of EDB residues, resulting from fumigation of these other commodities, would increase the estimated EDB dietary burden for its general use as a fumigant for stored grains.

Because residues of EDB entering the human diet from its use as a fumigant of stored wheat appears to dwarf its use as fumigant for all other grains, the Agency has focused its efforts on estimating the quantity of EDB contained in fumigated wheat and wheat products. The quantity of EDB in wheat, flour and bread varies considerably as a result of variations in the amount of EDB applied to stored wheat, duration between application and final use of product, type of storage facility used, and numerous other considerations. In order to determine the amount of EDB entering the human diet as a result of these registered uses, the Agency has considered all the available data on residues of EDB in wheat, flour and bread, obtained additional residue levels on these commodities through in-house studies, and developed several mathematical models which estimate expected EDB residues in these commodities at various points in movement through commerce.

Figure I (Holder, 1980) illustrates the typical movement of a shipment of grain through commerce. The top line indicates the general areas through which grain moves. Below this line are the Agency's estimated average periods for which the grain is held at each locus in commerce; the occurrence of EDB fumigations which the Agency has determined will be applied during the grain's movement through commerce; and a chronological list of the commerce areas through which the grain moves. As indicated in Figure I, the principal methods of grain distribution are export, animal feed, U.S. mills where grain is made into flour, and U.S. bakeries where flour is further processed to various baked goods.

The fumigation schedules shown in Figure I were used by the Agency (Holder, 1980) to estimate the concentrations of EDB in wheat and wheat products at each major point in its movement through commerce.

In addition to these time estimates, the Agency (Holder, 1980) developed three mathematical models (using results from laboratory studies) of the loss of EDB residues from wheat, wheat flour, and baked goods following post-harvest application of EDB. Using the schedule shown in Figure I, the Agency (Holder, 1980) calculated the "probable" concentration of EDB in bread to be 0.07 ppb, from which the resulting dietary burden of 1.8×10^{-7} mg/kg/day was estimated.

This same procedure was used to develop a "realistic worst case" estimate of the concentration of EDB at each point in commerce, and the dietary burden which would result from these concentrations. Using the same residue loss curves (RLC), but assuming a maximum application rate of EDB of 7.2 lbs/1000 bushels (instead of an average of 5.1 lbs./1000 bushels) and minimum treatment to market intervals, the Agency estimated the residue levels of EDB in bread and baked goods to be 31 ppb and an associated dietary intake of 3.3×10^{-5} mg/kg/day.

c. Fumigation of Grain Milling Machinery

In addition to residues of EDB that occur in wheat and wheat products as a result of grain storage fumigation, residues in many wheat products also result from the use of EDB in spot application to flour mill machinery and as a general space fumigant in these mills. The Agency has evaluated the three known studies (Wit, 1969, 1977, 1978) which have investigated the contribution of flour mill and machinery fumigation to EDB residue levels in wheat flour and baked breads (Holder, 1980). These studies generally involved sampling for EDB concentrations in incoming wheat, processed flour, and bread baked from that flour. Each of these sets of samples was taken at various times after spot fumigation.

Because the EDB concentration in the incoming wheat varied greatly from one study to the next, it is difficult to draw parallel conclusions from these three studies. The first two studies demonstrated that incoming washed wheat contained EDB, and that the resulting flour absorbed EDB from the spot-fumigated equipment (Holder, 1980).

In the Agency's opinion (Holder, 1980) the third and most recent study had such high levels of EDB in the incoming wheat that it probably "overshadowed any pick-up of EDB residues from the milling machinery due to spot fumigation." However, this study did show an increase in EDB residues in flour and bread up to 3-4 hours after spot fumigation. Using a time-weighted average of the differences between input wheat and the flour derived from the wheat, the Agency estimates that an average of 3 ppb of EDB persists in bread as a result of spot fumigation (Worthington, 1978). In the absence of the quantity of wheat flour processed annually through mills where EDB-treatment was used, the Agency has assumed that all flour mills fumigate with EDB. Using the residue level of 3 ppb, the Agency (Holder, 1980) estimates the dietary burden from spot fumigation for all wheat by-products to be 0.76×10^{-5} mg/kg/day, assuming all wheat by-products are equally contaminated with EDB.

Combining the dietary burden (DB) obtained for spot fumigation with the DB estimates for EDB used on stored grain, the Agency projects that the total contribution to dietary burden from residues in wheat and flour ranges from 0.34×10^{-5} to 4.1×10^{-5} mg/kg/day for all wheat fumigations (Holder, 1980).

In addition to these derived dietary burdens for all EDB fumigations, the Agency (Holder, 1980) has summarized data on residues of EDB measured in breads made with wheat treated with EDB. A total of 57 samples from 5 independent studies yielded an average observed residue level of EDB in bread of 38 ppb with a corresponding dietary burden of 4.1×10^{-5} mg/kg/day.

The Agency has efforts underway to obtain additional data on residues as they actually occur in commerce. The Benefits and Field Studies Division of OPP, in cooperation with the USDA's Federal Grain Inspection Service, has analyzed flour samples obtained from several of the USDA's programs for distributing flour to domestic charity programs, including the School Lunch Program (Marshall, 1980). Preliminary results of these analyses for EDB (Bontoyan, 1980) confirmed EDB residues in all of the samples analyzed in the first phase of this study.

Because this DB is derived from actual measurements of EDB residues observed in bread, it includes EDB residues resulting from both spot fumigation of grain milling machinery and grain storage fumigation.

It is worth noting the markedly good agreement between the DB of 4.1×10^{-5} determined from actual bread samples and the projected maximum DB of 4.1×10^{-5} derived from the assumptions and calculations discussed above

(Holder, 1980). Thus, the Agency concludes that the total dietary burden resulting from EDB fumigation of wheat in storage and of flour machinery is best estimated from the data collected from actual bread samples, which is 4.1×10^{-5} mg/kg/day.

For an "average" 60 kg individual in the U.S., this dietary burden translates into 2.5 micrograms of EDB consumed per day from the fumigation uses of EDB on stored grains. As discussed above, only fumigated wheat and wheat by-products were considered. The estimated dietary burden may slightly underestimate the actual DB resulting from the commercial use of EDB to fumigate stored grains. Considering the evidence currently available to the Agency, 4.1×10^{-5} mg/kg/day is the Agency's best estimate of the dietary burden resulting from all EDB fumigation.

d. Quarantine Fumigations

Several agricultural fruit and vegetable commodities are regulated by federal and interstate quarantines. These regulations were enacted to protect the importing state from the introduction of new insect or disease pests. U.S. quarantine treatments are legally mandated by authority of the Plant Quarantine Act of 1912 as amended (7 U.S.C. 151-167) and the Federal Plant Pest Act (7 U.S.C. 150aa, 150jj) through quarantine administrative instructions, and regulations. The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) is responsible for carrying out these mandates.

USDA regulations require treatment of imported commodities and of certain commodities transported out of quarantined regions (Table 10).

Table 10

U.S. Quarantine Requirements for EDB Treatment

Regulation	Commodities	Exporting Countries
7 CFR 318.13-45	bitter melons, bananas, litchi nuts, cucumbers, papayas, pineapples, cayenne, string beans, zucchini squash	Hawaii
7 CFR 318.58-3d	mangoes	Puerto Rico
7 CFR 319.56-2c	oranges, tangerines, grapefruits	Mexico and certain Central American countries
7 CFR 319.56-2j	mangoes, plums	Mexico, Guatemala

As a consequence of the U.S. quarantine requirements, EDB is registered as a commodity fumigant for post-harvest control of insects infesting citrus, tropical fruits (including mangoes, papayas, litchi fruit and nuts, and guavas), pineapples, bananas, cherries, plums, peppers, cucumbers, string beans, and zucchini squash. For many of these commodities, EDB is the only fumigant authorized by the USDA regulations. In addition, certain states also require fumigation of interstate transported commodities. In California, the State Administrative Code (section 3252) restricts importation of several citrus fruits from Puerto Rico and Florida. These commodities may only be received in the State after being fumigated at the point of origin in accordance with APHIS regulations.

EDB treatments are carried out in fumigation chambers as specified in Quarantine 13 (7 CFR 318.13), Quarantine 58 (7 CFR 318.58), and Quarantine 56 (7 CFR 319.56). Quarantine specifications call for the use of technical grade EDB of at least 97% purity, which is typically introduced into the fumigation chamber in the liquid state onto a home-variety electric frying pan for volatilization. This is the method used in Florida. An alternate method, used in Texas, involves the dripping of liquid EDB in front of a high speed fan. Because of the high density of EDB gas (more than six times heavier than air), forced circulation within the chamber is also required for volatilized EDB. The exposure period for both methods is two hours from the time all the required EDB has entered the chamber.

Over 99% of the 83,500 pounds of EDB used in 1977 for quarantine purposes was applied on citrus and tropical fruits (EPA, 1979). The remaining amount of EDB, less than 850 pounds, was used on an estimated 750,000 pounds of miscellaneous fruits and vegetables which constitute only miniscule percentages of the total U.S. production of each of these commodities (Zygadlo, 1978). The Agency recognizes that some EDB food residue exposure can occur from these minor uses. However, the national dietary burden which results from these minor uses is negligible and insignificant in comparison with that expected from EDB fumigation of citrus and tropical fruits (Table 13). Thus, these minor uses are not discussed further, although a maximum dietary burden of 18.8 $\times 10^{-3}$ mg/kg/day (Holder, 1980) could be expected if 100% of these minor crops were fumigated with EDB or an individual ate 100% of EDB-treated food.

There are some monitoring studies available on the residues of EDB in various fruits and vegetables resulting from quarantine fumigation with EDB. The studies show that, while EDB penetrates these commodities more rapidly and completely than it does grains, it also dissipates more rapidly from them (Worthington, 1978).

These limited data were compiled by the Agency (Worthington, 1978) to estimate the average EDB residues occurring in citrus and tropical fruits one day after fumigation. The Agency (Worthington, 1978) estimated the average EDB residues occurring in citrus and tropical fruits one day after fumigation to be 8.0 ppm and 6.0 ppm, respectively. Using these data and a residue loss equation, derived from the longest half-life time of two days, residues at any time (t) can be calculated. See Table 12 for calculated results.

Subsequent to these estimates the Agency obtained data from the State of California (Maddy, 1979b) on residues of EDB found in citrus and tropical fruits collected in 1979 from wholesale produce markets in that state. These fruits had been fumigated "to comply with USDA quarantine directives prior to entry into California." The Agency (Worthington, 1979) has evaluated these data, and summarized them in Table 11.

Table 11

Measured EDB Residues in Fruits Obtained from California Wholesale Produce Markets

Fruit	Period after Fumigation (days)	Number of Samples Taken	Range of EDB Residues (ppm)	Average EDB Residue Level (ppm)
Papayas	3 to 16	24	0.13 to 1.24	0.69
Oranges	8 or 16	9	0.06 to 6.35	1.37

The Agency (Worthington, 1979) has analyzed these data to determine if they support its estimate that one day after fumigation the EDB levels in citrus and tropical fruits are 8.0 ppm and 6.0 ppm, respectively, and has concluded that they do support these estimates. By taking the observed residue levels and the duration of these levels after fumigation, the Agency (Worthington, 1979) has extrapolated to one day after fumigation using dissipation equations. These results generally cluster around the EDB concentrations one day after fumigation as previously estimated (Worthington, 1978).

In order to calculate the most likely residue levels occurring in these commodities at the retail market, the Agency (Panetta, 1979) has obtained specific estimates of both the minimum and the average treatment-to-market intervals.

These time intervals and the initial residue levels were put into the residue loss equation discussed above to obtain estimates of residue levels in citrus and tropical fruit at the retail market (Table 12).

Table 12

Estimated EDB Food Residues Resulting From Required Quarantine Fumigation

Commodity	Estimated Initial Residue Level (ppm)	Estimated Market Residue Levels (ppm)	
		Maximum[a/]	Average[b/]
Citrus	8	1.42	0.425
Tropical Fruits	6	0.76	0.32

[a/] Maximum residue levels assume a minimum treatment-to-market interval of 6 days for citrus and 7 days for tropical fruits. [b/] average residue levels assume 7 and 9.5 days, respectively (Holder, 1980).

The last two steps in calculating the DB for the U.S. population resulting from EDB fumigation of citrus and tropical fruits are to multiply the estimated residue levels from Table 12 by the percent crop treated, and multiply this product by the food factor (i.e., % of human diet which the commodity represents). The percent crop treated and consumed in the U.S. was first estimated to be 1.7% for citrus and 72% for tropical fruits (Zygadlo, 1978).

The estimate of the percent of crop treated for citrus was amended (Luttner, 1980) to 2.6% because the original estimate did not include citrus which is fumigated and imported to the U.S. The estimates of the food factors are 3.8% and 0.03% respectively for citrus and tropical fruits.

Accordingly, the following DB estimates have been calculated:

	Maximum DB (mg/kg/day)	Average DB (mg/kg/day)
Citrus	3.5×10^{-5}	1.05×10^{-5}
Tropical Fruits	0.41×10^{-5}	0.17×10^{-5}

e. Control of Wax Moths in Beehives and Associated Equipment

There are two Federally registered products containing EDB for controlling the wax moth (Galleria mellonella) in stored honeycombs. [The label of one product states that it is to be used on "...empty combs and empty hives" (Reg. No. 10092-1), while the other label gives directions for use, "When bee combs and/or hives are stored for the winter..." (Reg. No. 5785-46)]. No tolerances have been established for either organic EDB or the inorganic bromide ion residues for the use of EDB on honeycombs, because both registrations were considered nonfood uses. Although these labels do not specifically prohibit the use of EDB on honey or comb wax, it is not normal practice among beekeepers to do so. There are no known data on the potential for indirect EDB contamination through translocation to edible honey or beeswax as a result of fumigating stored comb-bearing frames or comb foundations. The Agency believes that no residues in honey are likely to result. Consequently, this registered use is not expected to contribute to the dietary burden of EDB.

f. Other Registered Uses of EDB

The remaining registered uses of EDB involve non-food uses and are not included in the dietary burden estimates. These uses include vault fumigation of stored clothing, structural termite control, control of bark beetles in coniferous trees, quarantine treatment of regulated articles for Japanese Beetle (including soil, plants with roots, and grass sod), and parasitic nematode control (including nursery plots, greenhouses, and potting soil).

g. Summary of EDB Dietary Exposures Resulting from Registered Use Practice

Table 13 is a summary of the daily dietary burden resulting from each of the food uses of EDB. This table shows the dietary burden at current use levels to be 1.21×10^{-4} mg/kg/day and 6.31×10^{-3} mg/kg/day if 100% of the crops on which EDB is used were treated. Included in this table are the relevant input data used to develop the dietary burden at current use levels. These include the average treatment-to-market interval, estimated EDB residue level at the time of entry into the human diet, the percent of total human diet made up by the given commodity, and the current percent of the commodity which is treated with EDB. As shown in this table, fumigation of stored grains and post-harvest fumigation constitute over 90% of the dietary burden which results from registered EDB use practices. The table does not include soil fumigation, where no residues have been found.

Table 13

Total Dietary burden (DB) of EDB residues in the human diet resulting from all commodity fumigation uses*

Commodity	Average Treatment to Market Time (days)	Est. Residues at Time of Entry into the Human Dietary (ppb)	Food Factor % (of diet)	Commodity Currently Treated %	DB if all of Commod. is Treated (mg/kg/d)	DB at Current Use Levels (mg/kg/d)
1. All Grain Products (Bulk Fumigation)	218	122	13.8	2.5	4.0×10^{-3}	10.1×10^{-5}
2. Grain products (Spot fumigation)	1.0	0.003	10.1	100	0.76×10^{-5}	0.76×10^{-5}
3. Tropical Fruits	9.5	320	0.03	up to 72	0.42×10^{-5}	0.17×10^{-5}
4. Citrus	9.5	425	3.81	2.6	4.1×10^{-4}	1.05×10^{-5}
5. Cherries	5	3000	0.10	NEGL.	7.50×10^{-5}	0
6. Plums	5	3000	0.13	NEGL.	9.75×10^{-5}	0
7. Peppers	5	3000	0.12	NEGL.	9.00×10^{-5}	0
8. Cucurbits	5	500	2.78	NEGL.	3.48×10^{-4}	0
9. Bananas	5	1000	1.42	NEGL.	3.55×10^{-4}	0
10. String Beans	5	3000	0.98	NEGL.	7.35×10^{-4}	0
11. Pineapple	5	2500	0.30	NEGL.	1.88 x 10-4	0
		Totals			6.31 x 10-3	1.21 x 10-4

*Holder, 1980

2. Inhalation and Dermal Exposures

All registered pesticidal uses of EDB may result in inhalation exposure. Applicators may be exposed during transfer, mixing, loading and actual application operations, calibration and repair of equipment, and reentry into fumigated structures or fields. Other workers not involved in the actual application of EDB may be exposed, including those working at or near grain storage sites and mills which have been fumigated, citrus quarantine fumigation stations, apiaries where fumigation has been used to control wax moths in beehives, and fields fumigated with EDB. The general public is not likely to experience significant inhalation exposure, although some exposure may occur in areas near quarantine fumigation stations, bark beetle control operations, and structures which have been fumigated for termite control. The major use patterns (for which quantitative exposure data are available) involving EDB inhalation exposure and risk estimates for specific populations at risk are presented in the following discussion. They are: a. preplant soil fumigation, b. citrus fumigation, and c. grain mill fumigation.

a. Exposure from Preplant Soil Fumigation

Ethylene dibromide is applied as a liquid pre-plant soil fumigant from tractor-mounted tanks or cylinders, using chisel injection or plow-sole methods.

The injection chisels or plow soles normally remain in the earth as the tractor moves across the field, and are removed only when the applicator turns the tractor around at the end of each pass. A small quantity of EDB may be released above ground when the chisels or plow soles are removed.

When EDB is applied with chisels, a float, cultipacker or roller is dragged behind the chisels to seal the soil. When plow-sole applications are used, the chemical is metered in front of the plow on the soil surface and immediately covered with soil by the plow behind and to the side of the treated area. Less than 5% of EDB is applied using the plow-sole method. However, in the preparation of pineapple fields, EDB is soil injected under a plastic mulch which prevents rapid volatilization.

Tractor operators and other applicator personnel may be exposed through volatilization of EDB before and/or after the sealing of the soil. In addition, exposure may also result from the calibration, cleaning or repair of equipment, from equipment failure, and from transfer and loading operations.

EDB is generally applied by open system operations, in which the pesticide must be transferred from 30 or 55 gallon drums by hand, powered pumps or gravity flow devices into tanks mounted above the injection chisels. There is potential for applicator exposure by inhalation of vapors and skin contact with the liquid during these open system transfer operations.

There is also a closed system method of transfer, in which EDB is fed to the chisels or plow soles from cylinders prepackaged with valves and diptubes, or containing a convenient orifice for attachment of suction tubes. The Agency is currently studying (but has not yet determined) the effectiveness of closed system technology in reducing worker exposure for many chemicals, including EDB (Mittelman, 1980).

The time duration for transfer operations and application varies, but it is roughly 10 minutes (0.17 hrs) for each transfer operation and 1.75 hrs for each application operation (Mittelman, 1980).

The Agency has estimated the annual exposure duration for total soil fumigation operations by site. These estimates are presented in Table 14. The estimates assume that transfer operations occupy 10% of the total application time.

1) Inhalation Exposure

There are relatively few measurement data regarding applicator exposure to EDB. The only sources of information are reports by the California Department of Food and Agriculture (Maddy, 1979c), Dow Chemical's Industrial Hygiene Laboratory (Vaccaro, 1976), and the Great Lakes Chemical Corporation (White and McAllister, 1977). The Dow and Great Lakes studies were submitted as parts of the rebuttal responses of these two manufacturers (Rebuttal Nos. 78 and 3C). These studies have been analyzed by the Agency (Mittelman, 1980).

Column 1 of Table 14 identifies the soil fumigation operation or location for which EDB air concentration was measured. The only measurements listed are those in which individual activities were monitored, in order to properly assess worker exposure. Air samples were taken during application alone (with open and closed cab), during transfer operations, while respiratory equipment was in use, and at sites on the treated field during application and up to 48 hours afterward.

The average EDB concentration measured in air (milligrams of EDB per cubic meter of air) at each of the sampling sites is listed in column 2. The use of closed cab tractors and closed transfer systems apparently did not reduce exposure to applicators involved in these studies; however, closed system research is currently being carried out, and insufficient data exist at this time to evaluate the future impact of closed cabs and transfer systems on applicator exposure.

The range of concentrations measured in each location and the number of samples taken are listed in columns 3 and 4. The greatest range of concentrations was measured during application activity in an open cab tractor where the exposures ranged from 0.008 to 4.75 mg/m^3. No range is listed for closed system transfer operations because a single sample was taken.

2) Dermal Exposure

The CDFA study (Maddy, 1979c) included measurements of EDB levels in hand washings taken from tractor drivers. The five samples taken ranged from 0.52 to 30.90 ug, with an average of 8.38 ug. Actual dermal contact incurred during transfer of EDB was not measured; however, the Agency assumes that the actual dermal contact incurred during normal operations will be at the same or higher levels than those measured from the hand washing samples because some EDB is expected to have evaporated or penetrated the skin (Mittelman, 1980).

3) Combined Inhalation and Dermal Exposure

The Agency (Mittelman, 1980) has estimated total inhalation and dermal exposures for private (non-professional) persons who both apply and transfer

Table 14

Measured air concentration of EDB during specific soil fumigation practices (1)

Exposure Situations	Average concentration in air (mg/m3)	Range (mg/m3)	Number of samples
Application/Closed cab	1.66	0.26 - 3.29	(n=5)
Application/Closed cab charcoal filtered intake	1.27	0.61 - 2.61	(n=4)
Application/open cab	0.81	0.008 - 4.75	(n=21)
Transfer operation/open system	3.03	0.77 - 5.30	(n=2)
Transfer operation/closed system	5.60	-	(n=1)
Area samples at field level:			
(A) During application	0.17	0.008 - 0.96	
(B) 24 hrs post-application	0.02	0.0008 - 0.05	
(C) 48 hrs post- application	0.07	0.05 - 0.08	

(1) Mittelman, 1980

EDB during soil fumigation. These estimates, contained in Table 16, assume a constant respiratory rate of 1.2 m^3/hr for light physical activity (No heavy activity breathing rates were used), a constant ambient air concentration (average of monitored values), and a range of exposure duration (see Table 15). Exposure estimates have been made for each use site (columns 1 and 2).

The total respiratory intake of EDB (milligrams per year) is presented in column 3 as the sum of exposures resulting from transfer and application operations. It is assumed that the applicator performs the transfer operation himself; 100% retention of inhaled EDB is also assumed. Total respiratory intake has been calculated in the following way, using data given for peaches as an example:

Inhalation Rate x (Transfer Exposure + Applicator Exposure) = Total Exposure
For peaches: 1.2 m^3/hr [(0.06 hrs. x 3.03 mg/m^3) +
(0.54 hrs. x 0.81 mg/m^3)] = 0.7 mg.

Total estimated dermal exposures are presented in column 4. An average dermal exposure value of 4.53 micrograms per hour is assumed (Maddy, 1979a). This value is based on EDB levels in water from hand washings, and assumes that the hand contact is the largest source of dermal exposure. Therefore, the dermal exposure estimates given here probably underestimate actual total dermal exposures.

One hundred percent of the EDB remaining on the skin is expected to be absorbed, based on data for DBCP, a chemically similar compound (Mittelman, 1980). Total estimated dermal exposure has been calculated by multiplying average dermal exposure by the duration of exposure. The following example, for peaches, uses figures from Table 15.

Dermal x (Transfer + Application) = Total Exposure

4.53 ug/hr x (0.06 hrs. + 0.54 hrs.) = 0.003 mg

The total estimated annual exposure (milligrams per year) is listed according to use site in column 4. It is expressed as the sum of the inhalation and dermal exposures for each use site. Assuming a 70 kilogram applicator, the maximum estimated exposure to EDB is experienced by pineapple applicators and transfer-operators. The total estimated annual exposure for this use site ranges from 303.3 to 532.4 mg/yr.

Commercial (professional) applicators' exposures are unknown, but the Agency (Mittelman, 1980) estimates that the duration of exposure of the approximately 25 professional applicators nationwide is roughly four times as long as that of the estimated 13,200 potentially exposed private applicators, based on data received from Great Lakes Chemical Co. (1977).

The CDFA (Maddy, 1979c) and Dow (Rebuttal No. 78) studies reported airborne concentrations of EDB in the breathing zones of applicators while respirators were in use. Based on the data from these studies, the Agency (Mittelman, 1980) concluded that the use of respirators can effectively reduce inhalation exposure by a factor of 14 for half-face and 24 for full-face respirators, but the use of closed tractor cabs is not necessarily effective, based on current data that demonstrate higher exposures in closed cabs than in open cabs.

Table 15 Estimated annual duration of exposure to EDB to soil fumigation workers (1)

Site	Annual duration of exposure (hrs)[2] Transfer	Application	Estimated number of exposed applicators (private only)
Peaches	.06	0.54	670
Tobacco	1 - 2.5	9 - 22.5	10,800 maximum
Peanuts (FLA, ALA, GA)	1.2	10.4	35
Pineapples	24.5 - 43	220.5 - 387	45
Vegetables	1 - 5.2	9 - 46.8	414
Sweet potatoes	0.2 - 0.3	1.8 - 2.7	650
Irish potatoes	0.4 - 0.7	3.6 - 6.3	150
Cotton (CA)	10	90	25
Cotton (AR, GA, MS, NC)	2 - 6	18 - 54	410
Citrus (pre-plant)	2.5 - 3.2	22.5 - 28.8	1
Citrus (burrowing nematode containment program)	41.6 (aggregate duration of 52 man days)	374.4	unknown

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(1) Mittelman, 1980

(2) For purposes of estimating exposure, the Agency has assumed a uniform transfer duration of 10% of total exposure time. Exposure during transfer is less when drums are mounted on the application rig and pumping into a tank is not required. The extent of this practice is unknown.

Table 16 Total estimated annual exposure to EDB for private applicators/transfer operators during soil fumigation. (1/)

Use Site	Total respiratory Intake of EDB (mg/yr)			Total estimated dermal exposure (mg/yr)(2/)	Total exposure (mg/yr)
	Transfer	Application	Total		
Peaches	0.2	0.5	0.7	0.003	0.7
Tobacco	3.6-9	8.7-21.8	12.3-30.8	0.05-0.125	12.4-20.9
Peanuts	4.3	10.1	14.4	0.058	14.5
Pineapples	88.2-154.8	213.9-375.4	302.1-530.3	1.2-2.2	303.3-532.4
Vegetables	3.6-18.7	8.7-45.4	12.3-64.1	0.05-0.26	12.4-64.4
Sweet Potatoes	0.7-1.1	1.7-2.6	2.4-3.7	0.01-0.015	2.4-3.7
Irish Potatoes	1.4-2.5	3.5-6.1	4.9-8.6	0.02-0.035	4.9-8.6
Cotton (CA)	36	87.3	123.3	0.5	123.8
Cotton (AR, GA, MS, NC)	7.2-21.6	17.5-52.4	24.7-74	0.1-0.3	24.8-74.3
Citrus (preplant)	9-11.5	21.8-27.9	30.8-39.4	0.125-0.16	30.9-39.6
Citrus (burrowing nematode containment program)	149.8	363.2	513	2.08	515.1 (aggregate exposure)

(1) EPA. Mittelman, 1980. Assumptions are discussed in the text.
(2) Based on average dermal exposure of 4.53 ug/hr (Maddy, 1979).

4) Summary of Preplant Soil Fumigation Data

The data indicate that exposure to EDB results from all soil fumigation operations. The highest applicator exposures occur during transfer or loading operations. Exposures also result from broken hoses or other delivery lines and practices such as lifting chisels out of the ground while turning at the end of a row or passage and knocking off caked soil or organic debris from the chisels (Mittelman, 1980).

Data are not sufficient to estimate annual exposure resulting from dermal contact with EDB during soil fumigation. However, the Agency has collected data and estimated that EDB levels on the hands of tractor drivers range from 0.003 mg/yr for peaches to 2.15 mg/yr for pineapple (Mittelman, 1980).

More data are needed about the use of closed tractor cabs and closed transfer systems before their effectiveness can be evaluated. The Agency has been receiving comments on current efforts to develop a closed transfer system. EPA encourages such efforts.

b. Exposure from Citrus Fumigation

Ethylene dibromide is used in quarantine fumigation programs administered by the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA). Target pests include several species of fruit flies which may infest various fruits and vegetables exported from the U.S. or shipped from state to state.

Quarantine fumigation of citrus is carried out at commercial facilities in all major ports of entry in the U.S.. In Florida, the State Department of Agriculture conducts quarantine fumigation at its own facilities.

The Agency has obtained data on inhalation exposure to EDB associated with quarantine fumigation of grapefruit in Florida (Mittelman, 1980). Two large fumigation centers in Wahneta and Fort Pierce, which operate under a cooperative program between the USDA and the State of Florida, and a Tampa warehouse were selected for study by EPA to investigate worker exposure to EDB.

The fumigation centers consist of stations where whole truckloads of citrus are fumigated in large drive-in chambers. The Wahneta station has twelve chambers and the Ft. Pierce facility has sixteen. The individual fumigation chambers are designed to accomodate truck trailers loaded with approximately 1000 boxes of pre-packed citrus. After the chamber is loaded and closed, a predetermined amount of liquid EDB is dispensed into an electric evaporator to start the two-hour fumigation. After the fumigation has been completed, the EDB is exhausted from the chamber into the outside atmosphere, and the trailer is hooked up to the tractor rig for transportation to dockside warehouses; most frequently at the Port of Tampa.

Several groups of people may be exposed to EDB during fumigation operations: fumigation center employees; truck drivers, when they enter the chamber to hook up the tractor-trailer rig, and later when they open the trailer doors to unload fruit at the warehouses; warehouse and dock workers, who unload fruit from the trucks, sort and stack the fumigated boxes in the warehouse, and move the boxes to ships for loading. There is also some potential for exposure of people who live, work or drive in the vicinity of fumigation operations, from EDB exhaust in the atmosphere and the venting of EDB from departing trucks.

1) Data on Applicator Exposure

The Agency has assessed inhalation exposure data from a number of studies on fumigation station workers at Ft. Pierce and Wahneta, Florida and warehouse workers at Tampa, Florida (Mittelman, 1980). Estimates of the annual inhalation exposure to EDB for these occupationally exposed groups are presented in Table 17.

The Agency (Mittelman, 1980) calculated the average annual inhalation exposure to EDB in milligrams per kilogram per year, assuming a 70 kg worker, in the following manner:

Exposures

Wahneta-Indoor Operations

Avg. Concentraton of EDB	Breathing rate	Hrs./ day	Working Days/yr.

$$0.207 \text{ mg/m}^3 \times 1.8 \text{ m}^3\text{hr} \times 8.0 \times 112 - 70 \text{ kg} = 4.8 \text{ mg/kg/day}$$

These calculations assume a concentration of EDB that is based on the average of all survey samples taken at each site, a moderate breathing rate (assuming 50% of the work shift is spent in slack activity, and 50% in heavy activity) a 112-day season at the fumigation station, and a 155-day season at the citrus warehouse.

The figures in the table indicate that the workers inside the warehouse apparently experience the highest exposure to EDB. These exposure levels are estimated to be up to one hundred times the average yearly dose experienced by fumigation station workers.

Major fumigation treatment operations are also performed in Texas and Hawaii. However, these operations are slightly different from the method employed in facilities in Florida. In Texas, EDB is applied by dripping the compound into a high-speed blower rather than by evaporation. Of the 36 total facilities in the U.S., there are 25 commercial stations and a number of private operations in Texas. There are no known air sampling data available from these stations. In Hawaii, the fumigation of papayas, bananas, citrus, litchi nuts and cucumbers is performed by evaporating EDB from a heating pan. Treatment operations occur throughout the year. The fruit is hand-carried in field boxes into and out of the fumigation chambers. High potential for exposures therefore exist. The Agency estimates that a total of 12 APHIS and 6 State of Hawaii employees monitor and supervise the fumigation activities. Though measurements using detector tubes have failed to detect EDB levels in worker space, the limits of sensitivity of these methods are relatively high in the range of 1-100 ppm, as compared to .008 ppm in Florida measurements (Mittleman, 1980).

In addition to the personnel employed at fumigation stations and warehouses, other persons are potentially exposed to EDB through quarantine fumigation uses. At the Wahneta and Ft. Pierce stations and at the warehouses,

Table 17. Inhalation exposure of workers to EDB at citrus fumigation stations and at a citrus warehouse

Location	Workers	Concentration of EDB (mg/m^3) Ave. (7/)	Number of Samples	Breathing rate 5/	Hrs/day 1/	Days/yr 2/	Avg exposure to EDB (mg/kg/yr) 4/
Wahneta	Indoor operators	0.207	14	$1.8m^3$/hr	8	112	4.8
Ft. Pierce	Indoor operators	0.607	1	$1.8m^3$/hr	8	112	14
Wahneta	Outdoor operators	0.406	19	$1.8m^3$/hr	8	112	9.4
Ft. Pierce	Outdoor operators	0.280	2	$1.8m^3$/hr	8	112	6.5
Wahneta	Truckers/Station Personnel	0.048 8/	3	$1.8m^3$/hr	8	112	1.1
Ft. Pierce	Truckers/Station Personnel	0.092	1	$1.8m^3$/hr	8	112	2.1
Wahneta	Truckers	1.93	2	$1.8m^3$.hr	0.08	112 6/	0.4
Tampa	Forklift operators, Laborers (inside)	8.99	1	$1.8m^3$/hr	8	155 3/	287
Tampa	Forklift operators, Laborers (outside)	2.36	3	$1.8m^3$/hr	8	155 3/	75.3
Tampa	"Stickmen"	4.76	2	$1.8m^3$/hr	8	155 3/	151.8

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1. Hrs/day are very variable depending on work load during year. Average 8 hr. work day is assumed here.
2. Data from APHIS (1977)
3. Assuming 22 working days a month over the period of October 11 through May 14
4. Assuming a 70 kg worker
5. Assuming heavy activity (Spector, 1956).
6. Assuming trucker returns once each day
7. Avg. of 48 monitoring study samples
8. Including "non-detectable" samples at level of detection (0.008 $mg.m^3$).

there are private residences located a short distance from the station. This small non-occupational population may be exposed. Truck drivers transporting citrus to the Florida chambers are also potentially exposed for several hours while waiting at the fumigation station, and when entering the fumigation chambers for short periods of time (approximately 5 minutes) to couple and uncouple their vehicles. Very little data are available on the levels to which these populations are exposed.

2) Summary of Exposure Data for Citrus

The data indicate that significant exposures to EDB are encountered by workers in all phases of quarantine fumigation operations. The highest exposures apparently result from warehouse work. However, the limited data available from Florida fumigation centers indicate that high levels of EDB occur at these facilities. There are no data available on fumigation facilities in other states. It appears that there is high potential for exposure in Texas and Hawaii (Mittelman, 1980).

A number of other people are likely to be exposed to EDB from fumigation operations. These include truck drivers and the general population living or driving near fumigation facilities. Although those living in homes adjacent tofumigation stations are exposed to very low levels of EDB (.025 mg/m^3 to 0.852 mg/m^3) there may be significant numbers of people exposed (Mittleman, 1980).

c. Exposure from Grain Mill Fumigation

EDB is used as a "spot" fumigant in grain mills. This use is a consequence of regulations of the Food and Drug Administration and U.S. Dept. of Agriculture which specify maximum acceptable levels of insects or insect parts in processed foods. EDB is particularly effective in flour milling machinery and equipment. There are many ledges and obstructions where the product accumulates, and infestation tends to occur. Proper "spot" treatment of these critical areas prevents insect growth and reproduction. Typically, a formulation containing 70% EDB and 30% methyl bromide is used, although a mixture of 59% EDB, 32% carbon tetrachloride and 9% ethylene dichloride is also common.

Spot fumigations are performed on flour milling and cereal handling equipment after running the machinery until it is as empty as possible, leaving only small quantities of the product trapped in the equipment. The fumigant is typically applied by means of applicator gun injection into holes in the milling equipment designed specifically for this purpose. Spot fumigants are usually applied over a weekend when the mill is shut down and personnel are away. The fumigation period typically lasts about 24 hours, after which the mill is aerated prior to the return of the mill workers. Mill fumigations are repeated on a 3-4 week cycle in order to interrupt the 4-6 week life cycle of invading target pests.

In addition to spot fumigators who apply EDB, personnel involved in opening the mill and mill workers themselves are also potentially exposed to substantial quantities of EDB during start-up procedures. In some cases, the same mill personnel are involved in fumigation, aeration and start-up procedures.

1) Data on Grain Mill Fumigator Exposure

A report commissioned by the Millers' National Federation and prepared by Industrial Health Engineering Associates (IHEA, 1978) provides the only data available to the Agency on EDB exposures resulting from grain mill fumigation. IHEA measured exposure levels of EDB both inside and outside respirator face masks worn by selected applicators during fumigation operations at five different mills.

Based on the IHEA data, the Agency (Mittleman, 1980) has calculated a worst-case exposure for applicators of 50.8 to 59.3 mg/kg/yr. This exposure estimate assumes that the respirator is not worn tightly against the face or that it is removed during application, and that there is no rotation of applicators. Alternatively, with proper use of the respirator and no rotation of applicators, an inhalation exposure of 4.3-12.5 mg/kg/yr is estimated. The bases for calculating these figures are presented in Table 18.

2) Summary of Spot Fumigation Data

The IHEA study indicates that exposure to EDB can occur during and after spot fumigation. The highest levels of EDB were measured during the opening and start-up operations in grain mills. The data indicate that spot fumigators are potentially exposed and encounter significantly lower levels of EDB when respirators are properly worn.

Estimated exposures to EDB for workers associated with spot fumigation are presented in Tables 18 and 19. Workers involved in spot fumigation are usually also mill employees therefore, application, opening and start-up are included in the inhalation exposure estimate in Table 18. Table 19 presents the inhalation exposure estimate for those millworkers not involved in fumigation.

3) Conclusions

The Agency has reviewed and evaluated all of the available data on inhalation exposures to EDB. Uses of EDB for which data were available include soil fumigation, quarantine fumigation of citrus, and grain mill ("spot") fumigation. The populations at risk from these uses of EDB are listed in Table 20. The remaining registered uses of EDB are listed in Table 20 and include vault fumigation of stored clothing, control of bark beetles in coniferous trees, termite treatment, fumigation of beehive supers, and control of Japanese Beetles and parasitic nematodes. Exposure data were not available for these uses. Table 21 is a summary of the estimated average dose of EDB experienced by soil fumigation applicators, quarantine fumigators and spot fumigators. These estimates are derived from exposure data which was analyzed by the Agency (Mittelman, 1980).

C. Quantitative Assessment of Risk Data

1. Oncogenicity

The Agency's Interim Cancer Assessment Guidelines (41 FR 21402) state that when a chemical is judged to be a potential human carcinogen, the Agency will estimate its possible impact on the public health at current and anticipated levels of exposure. The Cancer Guidelines also recognize that the available

Table 18. INHALATION EXPOSURE OF SPOT FUMIGATION APPLICATORS TO EDB

Job Category (Spot fumigation applicator)	Activity 1/	Duration of activity (hrs) 2/	Average concentration of EDB in the breathing zone (mg/m^3) Range in parentheses 3/	Number of applications per year per applicator 4/	mg/yr inhalation exposure 5/	mg/kg/yr/inhalation exposure 6/
I a) Proper use of respirator b) Rotation of applicators	Spot fumigation	1.65	1.8 (level of detection 0.8 - 2.3 n=3)	1.6 - 4.7	299.1-878.7	4.3 - 12.5
	Fogging	1.2	4.6 (n=1)			
	Opening alone (aeration)	0.5	12.8 (1.9-26.9 n=6)			
	Opening + start up	1.8	39.9 (30.6-54.2 n=5)			
	Normal operation	6.2	3.8 (level of detection)			
II a) Improper use of respirator b) rotation of applicator	Spot fumigation	1.65	17.1 (n=1)	1.6 - 4.7	474.1-1392.8	6.8 - 19.9
	Fogging	1.2	34.2 (n=1)			
	Opening alone (aeration)	0.5	12.8 (1.9-26.9 n=6)			
	Opening + start up	1.8	39.9 (30.6-54.2 n=5)			
	Normal operation	6.2	3.8 (level of detection)			
III a) Improper use of respirator b) No Rotation of applicators	Spot fumigation	1.65	17.1 (n=1)	12-14	3556-4148.7	50.8-59.3
	Fogging	1.2	34.2 (n=1)			
	Opening alone (aeration)	0.5	12.8 (1.9-26.9 n=6)			
	Opening + start up	1.8	39.9 (30.6-54.2 n=5)			
	Normal operation	6.2	3.8 (level of detection)			

Footnotes for Table 18.

1/ Space fogging with organophosphates or bin fogging with methyl bromide may occur following spot fumigation with EDB. Should this be the case, additional exposure to EDB will occur due to volatilization of EDB from the machinery. The mill may be opened (aerated) several hours to a day prior to start up or may be opened and started up simultaneously (IHE, 1978). Normal operation involves the typical milling cycle on the first day of renewed operation.

2/ IHE, 1978. (average of five mills). Values for each fumigation cycle.

3/ IHE, 1978. Concentrations of EDB are assumed present at level of detection.

4/ Estimate based on 6-15 applicators/mills (Boyersmith, 1977) and 12-14 applications annually (DPRA, 1978). If two applicators work together and applicators are rotated, then each applicator performs 1.6 to 4.7 fumigation cycles annually:

$$\frac{\text{14 applications}}{\text{3 application teams}} = 4.7; \qquad \frac{\text{12 applications}}{\text{7.5 application teams}} = 1.6$$

5/ Assumption of 100% inhalation retention and 1.8 m^3/hr respiratory rate (Spector,1956). The same employees may or may not be involved in all five activities listed. It is assumed here that the spot fumigator is involved in spot fumigation, fogging, opening and start up, and normal operation. This is a conservative assumption made in the absence of any data categorizing actual use practices. Fogging is not always carried out in conjunction with spot fumigation, and aeration (opening) is sometimes performed several hours to a day prior to start up.

6/ Assuming a 70 kg worker.

Table 19. Inhalation exposure of mill workers

Job Category	Duration of activity (hrs)1/	Average concentration EDB in breathing zone (mg/m3)2/	Number of applications per year3/	mg/yr Inhalation exposure4/	mg/kg/yr Inhalation exposure5/
Mill worker	8	3.8 (based on level of detection in air)	12-14	656.6-766.1	9.4-10.9

1/ During first working day after fumigation.
2/ IHEA, 1978. Estimate based on level of detection in the IHE, 1978 study.
3/ DPRA, 1978.
4/ Assuming 100% retention of EDB and a respiratory rate for moderate activity of 1.8 m^3/hr (Spector, 1956).
5/ Assuming a 70 kg worker.

Table 20. Populations at Risk

Site	
Soil injection 1/	a) about 25 commercial applicators b) up to 13,200 farmer applicators
Florida citrus fumigation	a) 22 State employees b) 9 Federal employees c) 12-30 laborers per warehouse d) unknown number of truckers e) 3 fumigation stations
Texas citrus fumigation	a) 30 APHIS personnel b) 75 commercial personnel c) unknown number of truckers d) 25 fumigation stations
Hawaii fruit fumigation	a) 13 APHIS employees b) 10 State personnel c) unknown number of commercial personnel d) 15 fumigation stations
Grain storage 2/	a) 200 commercial applicators b) potentially 50,000 - 60,000 farmers
Spot treatment 3/	a) 2400 - 6000 potentially exposed spot fumigation applicators b) about 16,000 mill workers
Bark treatment	unknown
Termite treatment	unknown
Japanese Beetle control	unknown
Parasitic nematode control	unknown
Bee-hive supers4/	about 7000 beekeepers
Vault fumigation	unknown

1/ Mittleman, 1980.

2/ Mittleman, 1980.

3/ Estimate based on 6-15 applicators per mill (Boyersmith, 1977). Actual fumigation is performed on a rotational basis (2 per fumigation). Mill worker estimate from DPRA, 1978.

4 Mittleman, 1980.

Table 21 Summary table of inhalation exposure to EDB

	Average dose in mg/kg/yr
1. Soil injection	
Private Farmer/Applicator	1. 0.01 - 1.8[1]
2. Citrus Fumigation (Florida)	
a. Fumigation station: Corridor operators	2. a. 2.3 - 7.5
b. Fumigation station: Outdoor operators	b. 5.1 - 6.5
c. Truckers/Station personnel	c. 0.4 - 2.1
d. Warehouse: Indoor laborers	d. 287[2]
e. Warehouse: Outdoor laborers	e. 75.3
f. Warehouse: "Stickmen"	f. 151.8
3. Spot Treatment	
a. applicator	3. a. 4.3-59.3
b. mill worker	b. 9.4-10.9
4. Grain Storage Treatment	4. No Data
5. Bark Treatment	5. No Data
6. Bee-Hive Supers	6. No Data
7. Termite Treatment	7. No Data
8. Vault Fumigation	8. No Data
9. Japanese Beetle Control	9. No Data
10. Parasitic Nematode Control	10. No Data

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[1] This excludes pineapple use, for which the private applicator/loader dose may be as high as 7.6 mg/kg/yr. Specialized cultural practices may lower this dose significantly.

[2] Based on a single personal sample of 8.99 mg/m^3. Area samples, however, support the presence of such high concentrations (Mittelman, 1980).

techniques for assessing the magnitude of cancer risk to humans based on animal data are at best very crude. This is due to several causes, e.g., uncertainties in the extrapolation of dose-response data to very low dose levels and differences in levels of susceptibility in animals and humans. Accordingly, these risk estimates are neither scientific certainties nor absolute upper limits on the risk of cancer from exposure to EDB. The estimates should therefore be viewed as an index of potential health hazard that incorporates both the degree of carcinogenicity of the compound in animals and the measured, and/or estimated human exposures.

The CAG has estimated an individual's lifetime probability of EDB-induced cancers resulting from:

- ingestion of EDB in treated food commodities (CAG, 1980a)
- occupational inhalation exposure to EDB (CAG, 1980c)

Risk estimates for EDB dietary and occupational exposure were calculated using a standard one-hit no-threshold model based on the following general equations;

$$\text{Risk} = 1-e^{-Bx}; \text{ and}$$
$$B = (1/y) \ln [1/(1-P)];$$

where: B = slope coefficient of the one-hit model
$P = (Pt-Pc)/(1-Pc)$
Pc = incidence of tumors in control animals
Pt = incidence of tumors in test animals
y = test animal exposure (ppm)
x = potential human exposure (ppm)

As will be discussed below, the Agency adjusted the slope coefficient (B) of this equation to account for differences between exposure routes of the laboratory study used, which was gavage, and the estimates of amounts of EDB inhaled and consumed via dietary contamination.

a. Dietary Exposure

The CAG estimated cancer risks associated with EDB residues in the diet using the Agency's dietary exposure analysis (Holder, 1980), and the results of a long-term bioassay study of Osborne Mendel rats and B6C3F1 mice, completed by the National Cancer Institute (Hazelton Laboratories, 1975). EDB was administered by intubation for two years, causing a significant increase in the incidence of gastric tumors. The Agency used this study to derive a risk equation for lifetime exposure, measured in mg/kg/day. This equation incorporated both time and dosage in estimating tumor response rate.

The Agency recognized that use of the NCI study could be criticized because the dose delivered by gavage might not be comparable to dosing by ingestion or inhalation. As a result, the Agency adjusted the NCI tumor incidence results to account for the potential differences in tumor incidence which may occur because of differences in exposure routes. Through a comparison of the adjusted NCI figures with the results of a dietary DBCP study administered to CR albino rats (Hazelton Laboratories, 1977), the CAG derived an approximate estimate of the relative carcinogenic effectiveness of the two methods of administration and adjusted for EDB potency via the dietary route. To obtain an estimate of EDB potency via dietary ingestion, the intubation value for EDB ($B = 31.73$) was multiplied by the ratio of dietary to intubation parameters found for DBCP, which gave: B = 31.73 x 0.5897 = 18.71. This adjustment is based on the assumption that the ratio of oral to intubation tumor incidence is the same for EDB as for DBCP because the two pesticides are similar in both their chemical structure and their carcinogenic potential (CAG, 1979).

Estimates of cancer risks associated with EDB residues in the diet are illustrated in Table 22 which is based on "probable EDB dietary burden." The estimated lifetime probability of EDB-induced cancer is 2.6 x 10^{-6} for grain fumigation of wheat, 5.60 x 10^{-5} for soil fumigation, 2.7 x 10^{-5} for quarantine fumigation of tropical fruit, 5.1 x 10^{-5} for spot fumigation of wheat, and 1.8 x 10^{-4} for quarantine fumigation of citrus fruit. The total lifetime probability of EDB-induced cancer is 3.2 x 10^{-4}.

Table 23, based on "realistic worst case EDB dietary burden," shows the lifetime probability of EDB-induced cancer from general use categories. The probabilities range from a low of 6.6 x 10^{-5} for soil fumigation and quarantine fumigation of tropical fruit to a high of 5.7 x 10^{-4} for quarantine fumigation of citrus fruit. Other probability values are 1.2 x 10^{-4} for spot fumigation of wheat and 5.3 x 10^{-4} for grain fumigation of wheat. In summary, Table 23 shows that the average lifetime probability of EDB-induced cancer from residues in an average diet is 1.5 x 10^{-3}.

Table 24 lists the risks of EDB-induced cancer from ingestion of crops grown in soil fumigated with EDB. The range extends from 0 probability to 8.8 x 10^{-7} for melons. The total risk is 4.2 x 10^{-6}. This risk assumes that crops bear residues up to 0.001 ppm.

b. Non-Dietary Exposure

Risk estimates for those groups occupationally exposed to EDB are based on the Agency's "Non-Dietary Exposure Analysis for EDB Uses" (Mittelman, 1980), and the results of a recent study designed to assess the carcinogenicity of inhaled EDB to Sprague-Dawley rats. The Agency (CAG, 1980c) derived a direct estimate of the carcinogenic potency of inhaled EDB using a statistical model, adjusted for the lack of full lifetime exposures, and applied it to the results of this study. The Agecny used the significant tumor types found in the female rat to estimate the lifetime probability of a cancer case in humans. This lifetime probability was estimated to be:

$$P = 1-e^{-1.7X}$$

where:

X = estimated human lifetime average exposure

The CAG applied the above statistical model to the Agency's estimates of occupational inhalation exposure and numbers of people exposed. Table 25 presents the risks resulting from occupational exposures to EDB vapors. The exposure level presented in the second column of the table was obtained by the calculation $d = (40X)/(71.3 \times 365)$, where X is the exposure level in terms of mg/kg/year. It is assumed that of a theoretical 71.3 year lifespan, 40 years are spent in the occupation. Although the estimates of the lifetime probability of cancer presented in the table are in the high range, of particular concern are the risks to citrus warehouse workers whose estimated lifetime risks of EDB induced cancer can be as high as 4 chances in 10 of (CAG, 1980c).

The Agency (Mittelman, 1980) has estimated that from 50,000 to 60,000 workers in grain storage facilities are exposed to EDB. The risk to these workers cannot be estimated because the level of exposure is not known. Risk estimates for the lower volume uses of EDB were not calculated, because of a lack of exposure estimates.

2. Mutagenicity

As discussed earlier in this chapter, the presumption of mutagenic risk to humans from exposure to EDB has not been rebutted. The Agency concludes the human exposure to EDB also result in risk of mutagenic damage. The Agency is also developing Mutagenicity Risk Assessment Guidelines that will be utilized by the Agency for various chemicals as needed.

3. Reproductive Effects

As discussed earlier in this chapter, the presumption of risk of reproductive effects to humans from exposure to EDB has not been rebutted. No quantitative reproductive risk estimates will be developed, because the available health studies were determined to be inadequate to support a quantitative assessment.

4. Summary and Conclusions

The Agency has applied results from laboratory studies in estimating the individual lifetime probability of EDB-induced cancers from both dietary and occupational exposures. The dietary risk estimates from all registered uses range from 3.2×10^{-4} for the "probable dietary burden", to 1.5×10^{-3} for the "realistic worst case dietary burden", with quarantine fumigation contributing 2.1×10^{-4} and 6.4×10^{-4} to the respective ranges. The occupational risks of EDB-induced cancers resulting from inhalation of EDB vapor range from 1.8×10^{-5} to as high as 4 chances in 10 for citrus warehouse laborers.

Although the Agency concludes that there is a risk that mutagenic damage and reproductive disorders could result from exposures to EDB, the Agency has not quantified these risks.

D. Risks of the Alternative Pesticides to EDB

Table 26 summarizes all of the known risks for major alternative chemicals to EDB. These seventeen pesticides could be substituted for EDB depending upon the use that was cancelled. The regulatory status for each is also given. Four of the substitute chemicals are either on the RPAR list or candidates for RPAR, and most are restricted to use by certified applicators. In Chapter V, the risks of each substitute are compared to EDB on a use-by-use basis.

TABLE 22

ESTIMATES OF THE CANCER RISK DUE TO "PROBABLE EDB DIETARY BURDEN"

Source	EDB dietary burden (mg/kg/day)	Lifetime probability of EDB-induced cancer
Soil Fumigation	2.6×10^{-7}	5.6×10^{-5}
Grain Fumigation (wheat)	1.8×10^{-7} (4.1×10^{-5})	2.6×10^{-6} (6.28×10^{-4})
Spot Fumigation (wheat)	3.2×10^{-6}	5.1×10^{-5}
Quarantine Fumigation:		
Citrus	1.1×10^{-5}	1.8×10^{-4}
Tropical fruit	1.7×10^{-6}	2.7×10^{-5}
Total	1.6×10^{-5} (5.7×10^{-5})	3.2×10^{-4} (9.0×10^{-4})

The parenthesized value (4.1×10^{-5} mg/kg/day) is calculated from 57 samples of residue. Non-parenthetical values were derived from models using application rates. (Litton Bionetics, Inc., 1978).

TABLE 23

ESTIMATES OF CANCER RISK DUE TO "REALISTIC WORST CASE EDB DIETARY BURDEN"

Source	EDB dietary burden (mg/kg/day)	Lifetime probability of EDB-induced cancer
Soil Fumigation	4.1×10^{-6}	6.6×10^{-5}
Grain Fumigation (wheat)	3.3×10^{-5}	5.3×10^{-4}
Spot Fumigation (wheat)	7.6×10^{-6}	1.2×10^{-4}
Quarantine Fumigation:		
Citrus	3.5×10^{-5}	5.7×10^{-4}
Tropical fruit	4.1×10^{-6}	6.6×10^{-5}
Total	8.4×10^{-5}	1.5×10^{-3}

TABLE 24
UPPER BOUND CANCER RISKS DUE TO INGESTION OF CROPS GROWN IN SOIL FUMIGATED WITH EDB

Crop	Maximum expected residue ppb	Estimated dietary burden at current use level in mg/kg/day	Lifetime probability of EDB-induced cancer
Asparagus	1	0	0
Broccoli	1	2.4×10^{-9}	3.8×10^{-8}
Carrots	1	2.5×10^{-8}	4.0×10^{-7}
Cauliflower	1	5.6×10^{-10}	9.0×10^{-9}
Corn, sweet	1	0	0
Cotton	1	7.5×10^{-11}	1.2×10^{-9}
Cucumbers	1	5.0×10^{-8}	8.0×10^{-7}
Eggplant	1	1.1×10^{-10}	1.7×10^{-9}
Lettuce	1	6.6×10^{-10}	1.1×10^{-8}
Lima Beans	1	2.1×10^{-8}	3.4×10^{-7}
Melons	1	5.5×10^{-8}	8.8×10^{-7}
Okra	1	1.2×10^{-8}	2.0×10^{-7}
Parsnips	1	0	0
Peanuts	1	9.0×10^{-11}	1.4×10^{-9}
Peppers	1	0	0
Pineapples	1	2.0×10^{-8}	3.3×10^{-7}
Potatoes	1	1.5×10^{-8}	2.4×10^{-7}
Squash	1	0	0
Strawberries	1	2.0×10^{-9}	3.2×10^{-8}
Sweet Potatoes	1	5.4×10^{-9}	8.7×10^{-8}
Tomatoes	1	4.9×10^{-8}	7.8×10^{-7}
		2.6×10^{-7}	4.2×10^{-6}

Table 25
CANCER RISK DUE TO OCCUPATIONAL INHALATION OF EDB

Exposed group	Range of exposure (mg/kg/day)	Lifetime probability estimates	No. of workers exposed
Soil injection farmer applicator	$1.5 \times 10^{-5} - 2.8 \times 10^{-3}$	$1.8 \times 10^{-5} - 3.2 \times 10^{-3}$	13,200
Fruit fumigation(3)			
station corridor operator	$3.5 \times 10^{-3} - 1.2 \times 10^{-2}$	$4.1 \times 10^{-3} - 1.3 \times 10^{-2}$	11(1)
station outdoor operator	$7.8 \times 10^{-3} - 10.0 \times 10^{-3}$	$9.1 \times 10^{-3} - 1.2 \times 10^{-2}$	10
trucker/station personnel	$6.2 \times 10^{-4} - 3.2 \times 10^{-3}$	$7.2 \times 10^{-4} - 3.8 \times 10^{-3}$	10
Warehouse(3)			
Indoor laborer	0.4	0.4	4-10(2)
Outdoor laborer	0.1	0.1	4-10
Stickman	0.2	0.2	4-10
Spot fumigation			
Applicator	$6.6 \times 10^{-3} - 9.1 \times 10^{-2}$	$7.7 \times 10^{-3} - 0.10$	2400 - 6000
Millworker	$1.5 \times 10^{-2} - 1.7 \times 10^{-2}$	$1.7 \times 10^{-2} - 2.0 \times 10^{-2}$	16,000

(1) Assumed that 31 federal and state employees are evenly distributed.

(2) Per warehouse. Seasonal variation. Assumed that 12-30 laborers per warehouse are evenly distributed.(Mittelman, 1980)

(3) Figures are for Florida only. No data are available as to exposures in Texas or Hawaii.

Table 26 Human Hazards of Substitutes for EDB

(* - most likely alternative if all EDB uses were cancelled)

Chemical	Potential Hazards to Man	Regulatory Status
Aldicarb	Acutely Toxic	Some uses restricted Others under evaluation
*Aluminium Phosphide	Acutely Toxic Explosive	All uses are restricted
Carbofuran	Anticholinesterase Reproductive Effects Acutely Toxic Immuno-suppressant	Most uses restricted Others under evaluation
*Carbon Disulfide	Explosive (Tox Profile was not done-literature being assembled)	Most uses restricted
*Carbon Tetrachloride	Oncogenicity Mutagenicity Nephrotoxicity Hepatotoxicity	Notice of RPAR issued 10/15/80.
Chloropicrin	Lung Irritant Skin Irritant Acute Toxicity	Most uses restricted
Dasanit	Anticholinesterase	No action
D-D (contains 1,3 dichloropropene)	Oncogenicity Lung, liver & kidney damage Mutagenicity Eye & skin irritant	See Telone
*Ethylene Dichloride	Oncogenicity Mutagenicity	Accepted for pre-RPAR
Hydrogen cyanide	Acutely Toxic	All uses restricted

Human Hazards of EDB Substitute Chemicals - (cont'd)

Chemical	Potential Hazards to Man	Regulatory Status
*Methyl Bromide	CNS lesions Skin irritant Mutagenicity	Most uses restricted Accepted for Pre-RPAR review
Mocap	Anticholinesterase Acute toxicity	Some uses restricted Others under evaluation
Nemacur	Eye & skin irritant	Liquid formulations are restricted Granular formulations are proposed for restriction
Paradichloro benzene	Oncogenicity	Accepted for pre-RPAR
Silica aerogel	Eye Irritant	No Action
Telone (1,3 dichloropropene)	Oncogenicity Mutagenicity (*in vitro*)	Accepted for RPAR
Vorlex (contains 1,3 dichloropropene	Eye & skin irritant	See Telone

references: Federal Register, 1978
Federal Register, 1979a
Federal Register, 1979b
Mishra, L; 1978b

III. BENEFITS SUMMARY FOR ETHYLENE DIBROMIDE

A. Introduction

EDB is used for a variety of agriculturally related activities. It is produced in the U.S. by the Great Lakes Chemical Corporation and Dow Chemical Company, and its production and marketing data are confidential. However, it has been estimated that in recent years approximately 13 to 15 million pounds of EDB have been used annually as a pesticide active ingredient. Sites treated include: preplant soil fumigation of agricultural crops (tobacco, pineapple, citrus, peaches, peanuts, cotton and various vegetables); fumigation of stored beehive supers; termite control; fumigation of stored grain; spot fumigation of flour milling machinery; for Federal (APHIS) quarantine programs; and on felled logs for control of bark beetles.

Estimates of annual usage were made in 1978 by the USDA/State and EPA Cooperative Assessment Team. In 1979, DBCP, one of the major alternatives to EDB, was largely banned from the market. This most likely resulted in some increase in EDB usage for certain sites. Because it was not possible to determine the magnitude of these increases, the original 1978 estimates of annual usage were used as a base for most of the sites analyzed.

Benefits analyses for all sites except stored grain and flour mills were prepared jointly by economists of EPA and USDA (Abbreviated Benefits Analysis of Pesticidal Uses of Ethylene Dibromide, January, 1979). Analyses of flour mills and stored grain were performed under EPA contract by Development Planning and Research Associates, Inc., of Manhattan, Kansas.

The alternatives to EDB were chosen on the basis of cost, efficacy, and availability. Economic impacts of alternatives were estimated using partial budgeting. This methodology allowed measurement of the change in control costs and yield, if any, while holding all other inputs and their costs constant.

Cancellation of all current uses of EDB are expected to result in annual losses to users of approximately $60.0 million (Table 27). This represents losses due to both increased cost of treatment and decreased value of production for certain crops. The largest single impact would be noticed through the APHIS citrus quarantine program, where shippers and producers could suffer a net loss of $24 million, and where balance of payments deficits could increase by approximately $18 million, if the export market to Japan were lost.

In calculating these impacts, it was assumed that only currently registered pest control methods would be available at the time EDB cancellation becomes effective. Over 30% of the estimated impact of $60 million would occur in the APHIS quarantine program for which there are no known chemical alternatives to EDB. Extensive research conducted in recent years demonstrates that the use of gamma radiation can be an effective pest control method (Interdepartmental Committee on Radiation Preservation of Food, December 1978). A number of foreign countries and the U.S.A. have approved irradiation of certain food products for human consumption (Appendix II). Though irradiation of wheat, wheat flour and white potatoes has been approved in the U.S., the Food and Drug Administration, the Federal body responsible for these approvals, has not yet resolved a 1973 petition (FAP #3045) from USDA requesting approval of the use of gamma irradiation on papayas and citrus. Should this pest control method be approved and accepted by foreign export markets, the impacts of cancelling EDB may be reduced significantly.

B. Fumigation of Stored Grain

EDB is used in combination with ethylene dichloride and carbon tetrachloride for insect control in stored grain. A total estimated 630,000 pounds of EDB active ingredient are used annually in grain storage facilities: 409,000 pounds are applied on farms, while 221,000 pounds are used in commercially stored grain. Approximately 225 million bushels of stored grain, or about 2% of the grain produced in the country, are treated annually with fumigants containing EDB.

The most likely alternative to EDB-containing mixtures is the 80%/20% mixture of carbon tetrachloride and carbon disulfide at on-farm storage facilities, and aluminum phosphide at off-farm storage centers. Because on-farm and off-farm facilities vary greatly in air-tightness the substitutes also vary; the tighter the facility, the more likely it is that the substitute would be aluminum phosphide. When used as directed, both carbon tetrachloride/carbon disulfide and aluminum phosphide will be less costly than EDB. As a result, fumigation costs will actually decline if EDB becomes unavailable and is replaced with these alternatives. The Agency estimates a $500,000 to $2,260,000 annual savings from use of these EDB alternatives.

Another alternative treatment method which is effective against a broad spectrum of pests of stored grain is the use of a controlled atmosphere of carbon dioxide, nitrogen and combustion products of natural gas. These gases can be circulated through a sealed bin, reducing the oxygen in the bin atmosphere to a very low level and killing any pests. In all cases, bins must be sealed tightly, grain temperatures must exceed 70° F. and the exposure time must be at least four days. The commodities are not contaminated with any chemical residues. The performance of this treatment method is optimum in silos and other readily sealed sites, but use in flat bed storage is unlikely. In response to a petition for exemption from tolerance submitted by the USDA IR-4 minor use program, the Agency has proposed to grant this exemption (Federal Register, Vol. 45, No. 136, July 14, 1980, p. 47168). Commerical acceptance and use of this controlled atmosphere method could occur once the exemption from tolerance is made permanent; thus, another alternative for this use of EDB could become available. The Agency has no information regarding the costs of such a treatment system and would be interested in obtaining such information from any knowledgeable party.

C. Quarantine Fumigation of Citrus, Tropical Fruits and Misc. Fruits and Vegetables.

USDA's Animal and Plant Health Inspection Service (APHIS) requires the use of EDB in its quarantine program to destroy certain fruit flies before they become established in parts of the U.S. For the same reason, Japan also requires that all fresh grapefruit imported from the U.S. be treated with EDB. The target flies include the Mediterranean, Caribbean, West Indian, Oriental, Melon, Queensland, and the Cherry fruit fly. In 1977, approximately 83,500 pounds active ingredient of EDB were used to meet the requirements of APHIS and Japan.

There are currently no registered chemical alternatives to EDB for quarantine purposes. Vapor heat (112°F for 4-6 hours, followed by chilling) and cold storage (36°F for 10-22 days) can control these flies as effectively as EDB, however, its use often results in varying and considerable degrees of fruit damage.

Table 27. Annual Economic Impacts of Cancelling Ethylene Dibromide

Use sites	Active Ingredient Applied	Extent of use (Units Treated)	Change in Cost of Treatment	Decrease in Value of Production	User Impacts	Market/ Consumer Impacts	Balance of Payment Impacts
	Thousand pounds		thousand dollars.1/				
Tobacco	2,100.0	77,600 acres	1,200.0	0	1,200.0	none	0
Pineapples	572.4	11,500 acres	281.5	1,218.5	1,500.0	minor	0
Citrus							
A. Preplant	20.0	100 acre	3.5	0	3.5	none	0
B. Burrowing nematode containment	252.0	500 acres	44.0	0	44.0	none	0
Peaches 2/	170.0	2,000 acres	20.3 to 118.2	0	20.3 to 118.2	none	0
Forestry 3/	20.0	68,000 acres	7.4 to -15.8	unquantifiable	7.4 to 15.8	none	0
Termites	20.0	12,400 structures	unknown	-	-	none	0
Grain Storage	630.0	125.7 to 392. 0 mil. bu.	-2,258.0 to -500.0	0	2,258.8 to -500.0	none	0
Flour Milling	465.0	391 mill	4,000.0 to 7,700.0	0	4,600.0 to 7,700.0	$0.016 to $.028 per capita	0
Quarantine (APHIS)	83.5	494.5 mil. lbs.	538.9	24,164.0	24,702.9 4/	price reduction for grape-fruit; price increase for papayas & mangoes	18,384.0
Peanuts	4,197.4	257,390 acres	2,500.0	11,000.0	13,500.0	none	0
Cotton	721.8	55,600 acres	435.7	0	435.7	none	0
Vegetables	5,600.0	180,000 acres	3,800.0	0	3,800.0	none	0
Honey combs	20.0	5,679,000 supers	3,686.2	6,500.0	10,186.2	minor/none	0
Total	14,872.1	-	14,895.0 to 19,776.2	42,882.5	57,775.5 to 62,658.7	-	18,384.0

1/ 1978 dollars.

2/ Assumes reregistration of DBCP. If DBCP is permanently cancelled, economic impacts would range from approximately $379,000 to $610,00 annually.

3/ Including residential use.

4/ Primarily borne by the growers rather than the actual users. (APHIS Program of EDB).

An additional method, gamma irradiation, shows promise as a substitute for EDB post-harvest fumigation. However, as discussed above, the Food and Drug Administration has not reached a decision on approval of the use of irradiation on fruits and vegetables.

Loss of EDB may result in economic impacts to fruit and vegetable shippers, producers, and consumers. Shipper impacts would result from an approximate 700 percent increase in treatment costs, from $0.87 per 1,000 pounds of commodity using EDB to $6.25 per 1,000 pounds of commodity using either vapor heat or cold storage treatments. Changes in imports and exports of grapefruit, tropical fruits and miscellaneous vegetables would result in anestimated balance of trade deficit of $18 million annually, assuming Japan would not accept non-EDB treated grapefruit. However, if Japan agrees to accept grapefruit treated with alternative methods, this balance of trade deficit would be eliminated. These impacts are summarized by commodity as follows:

1. Grapefruit

Under current trade agreements, a cancellation of EDB could result in a loss of exports to Japan due to Japanese regulations which require EDB treatment. A loss of exports would result in decreased treatment costs of $263,300, while shipments of grapefruit by other shippers (imports and interstate) would result in increased treatment costs of $265,000 (vapor heat or cold storage), resulting in a net increase in treatment costs of $1,700. Under current trade agreements, the domestic market would have to absorb the grapefruit previously shipped to Japan (about 20 percent of domestic fresh consumption) which would result in price reductions and an estimated decrease in the annual value of production of over $29 million and a balance of payments loss of over $27 million. If Japan agrees to import grapefruit treated by alternative methods (vapor heat, cold storage, or gamma irradiation), the economic impacts of cancellation would be significantly reduced. Specifically, treatment costs of fruit exported to Japan would increase $1.6 million annually with the use of vapor heat or cold storage (changes in treatment costs with the use of irradiation have not been evaluated). Also, there would be no loss in the U.S. value of production (due to excess supplies) and the $27 million balance of payments loss would not occur.

2. Papaya

Cancellation of EDB could result in a loss of exports to Japan due to Japanese regulations requiring EDB treatment for papayas. A loss of exports would result in reduced treatment costs of $2,700 and a loss in revenue of $1.2 million. Interstate shipment would result in increased treatment costs of $73,500 for a net increase in treatment cost of $70,800. The alternative treatment methods of heat or cold would result in a high level of fruit damage. Although papayas would no longer be exported to Japan, the amount of fruit damaged would exceed the previous level of exports. Therefore, domestic supplies would decrease and prices of papaya would increase.

3. Mango

Cancellation of EDB would result in a loss of imports of mangoes. This loss would result in decreased annual treatment costs of $10,900. The domestic producers would not have competition from imports, resulting in short term price increases and an increase in the value of domestic (untreated) product estimated at $2,104,000 per year.

4. Other Citrus

Cancellation of EDB would result in increased treatment costs of $473,400 per year due to use of alternative treatments. The alternative treatments would result in product damage with a decrease of $2,003,000 in product value.

5. Miscellaneous Fruits and Vegetables

A cancellation of EDB would result in increased treatment costs of $7,600 due to use of alternative treatments. The alternative treatments would result in decreased value of product of $31,000 per year because of product damage from use of alternatives.

6. Summary of Quarantine Fumigation Impacts

The overall impact of EDB cancellation on the APHIS Quarantine Program would amount to an estimated increased annual treatment costs of $538,900 and an estimated decrease in the value of production of $24,800,800 per year. In the short term, consumers would have price decreases for grapefruit and price increases for papayas and mangoes. The magnitude of these increases was not estimated due to a lack of data. In the longer term, production adjustments would result in price changes that would partly offset the short term impacts.

Under current trade agreements, the cancellation of EDB usage in the APHIS quarantine programs would have an adverse impact on the U.S. balance of payments. This total impact, roughly estimated at $18.4 million, would eventually be borne by the consumer. The major factor would be the $27.4 million loss in the export market of grapefruit to Japan. In addition, export market of papayas to Japan, valued at $1.2 million, would be lost. Mangoes, valued at $8.2 million, would no longer be imported. Other imported commodities previously treated with EDB would be damaged, resulting in a $2.0 million positive impact on the balance of payment position.

D. Spot Fumigation of Grain Milling Machinery

EDB has been used for over 20 years as a spot fumigant for control of insect populations which invade flour milling equipment. Currently, an estimated 465,000 pounds of EDB active ingredient are used annually for this use. A 70 percent EDB and 30 percent methyl bromide combination is common, although other EDB formulations are also used. The only alternative spot fumigant that does not contain EDB is a mixture of 75 percent ethylene dichloride and 25 percent carbon tetrachloride. However, the dosage required for this pesticide is so large that the milling industry does not consider this mixture to be a viable substitute. It must be used more frequently (two to four times that of EDB fumigants) to exert any reasonable degree of control. The large amount of liquid material applied may cause the system to clog, requiring extra preparation time before milling can be resumed. The overall results of using this alternative mixture include the actual application of a much greater quantity of chemicals, a higher cost for fumigant, the use of more labor, and more down time of the mill. Carbon tetrachloride is also an RPAR candidate. If that compound were cancelled, then no spot fumigant would remain.

The only viable alternative to spot fumigation is general fumigation of the entire mill space. Methyl bromide and aluminum phosphide are currently the two most commonly used general space fumigants, accounting for approximately 75 and 25 percent, respectively, of the general space fumigant market.

The principal economic impact resulting from the cancellation of EDB as a spot fumigant in flour milling equipment would result from the increased cost of substituting general fumigation of the entire mill space (with methyl bromide or aluminum phosphide) for the current practice of spot fumigation of individual items of milling equipment.

It is projected that an average of four general fumigations per year would be required to achieve satisfactory control. The current practice is 12-14 spot fumigations and one general fumigation annually. Thus, the change would require that mills undertake three additional general fumigations per year but save 12-14 spot fumigations.

Based on the relative cost of the present versus the projected systems, the most likely increase in annual costs would be a total of $3,800,000 in the wheat, durum, and rye milling industries and $800,000 in the dry corn milling industry, respectively. These impacts would result in direct costs of $14,000 per year in wheat and rye mills and $8,600 in dry corn mills. Based on total human consumption of wheat, durum and rye flour, and dry corn mill products, the consumer impacts would be small, approximately 1.6 cents per person.

If five rather than four general fumigations are necessary per year, wheat and rye mill costs would increase $6.4 million annually, and corn mill costs would increase $1.3 million annually, resulting in increased costs of approximately $21,500 and $14,000 per mill, respectively. Based on total human consumption of wheat, durum, and rye flour and dry cornmill products, the consumer impact under the more conservative estimates would continue to be small--approximately 2.8 cents per person per year.

E. Preplant Soil Fumigation

1. Tobacco

EDB is used to control root-knot, root lesion, and stunt nematodes on flue-cured tobacco in Florida, Georgia, North Carolina, South Carolina and Virginia. Approximately 2.1 million pounds of EDB as an active ingredient were used in 1977, two-thirds of this in North Carolina.

Alternative registered chemicals to EDB include other fumigants (DD and Telone II), multi-purpose fumigants (Telone C-17, DD/Pic, Vorlex), and non-fumigants (ethoprop, fensulfothion, carbofuran and oxamyl). Even without use of EDB, nematodes could be eliminated, through an integrated pest management program involving rotation, setting healthy transplants, and early root and stalk destruction. Growers switching from EDB to other fumigants or from multi-purpose formulations containing EDB to other multi-purpose fumigants would not experience any significant change in yield regardless of nematode population levels, but the alternatives to EDB are more expensive.

If EDB were to become unavailable, tobacco growers would spend approximately $1.2 million more for control than they currently spend using EDB. These increased control costs represent an increase in total production costs of approximately 1.2 percent. Long run economic impacts to tobacco growers would be slight. Likewise, little if any impact would be noted at the market or consumer level if this registration of EDB were cancelled.

2. Pineapple

All commercial U.S. pineapple production is located in Hawaii, and all Hawaiian pineapple acreage must be treated with nematocides. Damage is caused either by the root-knot nematode or the reniform nematode. Approximately 572,400 pounds of EDB are used annually for nematode control on Hawaiian pineapple fields. The alternative to EDB is DBCP applied either in combination with DD or Telone. Depending on soil conditions and species of nematode present, each of these nematocides has its unique place in nematode control programs. EDB is used on approximately 11,500 acres subject to high soil moisture.

Since pineapple is a perennial crop (with a normal rotation of 4 years), only one-fourth (2,875) of the above mentioned 11,500 acres needs treatment annually. Substitution of a combination of DBCP and DD for EDB on this acreage would result in yield losses of approximately 4.8 percent, as well as increased control costs of about $98 per acre. 1979 price increases in DBCP relative to other nematocides could further increase these costs by $75 per acre since DBCP prices have increased from $9.35 to $20.00 per gallon. The present net value of the combination of these economic impacts, (estimated at 1977 dollars and prices) over the entire production cycle following removal of EDB (a 5 1/2 year period), is estimated at $5.3 million (using a 7 per cent discount rate). In the long run, approximately $1.5 million additional cost per year would be paid by Hawaiian pineapple growers until a satisfactory substitute for EDB is registered for use. Minor market or consumer impacts are expected.

3. Citrus

EDB is registered for preplant use in fruit tree planting sites, including citrus groves. Target pests are the citrus nematode and the burrowing nematode. EDB use in citrus (preplant) has been estimated at 20,000 pounds active ingredient annually. This quantity would treat approximately 110 acres, or less than one percent of new citrus acreage planted annually. The most viable alternatives to EDB for preplant citrus use are DD and Telone.

A second use of EDB in citrus is barrier establishment and maintenance to control the burrowing nematode in Florida conducted under a cooperative Federal-State Program. In this program, about 250,000 pounds active ingredient annually are chisel-injected in barrier zones ranging in width from 16 to 32 feet.

Economic impacts associated with cancellation of EDB for preplant use on citrus are expected to be minimal. In these preplant situations, use of alternatives will increase direct treatment costs by an amount ranging from $17.50 to $45.50 per acre depending on the alternative nematocide selected. However, because of the low volume use of EDB for this use site, total cost increases to affected growers will be only $3,500 per year. In the burrowing nematode control program, use of alternatives will increase program costs from $25,000 to $63,000 per year, depending on the alternative chemical chosen.

No short-term market or consumer effects are anticipated as a result of this EDB restriction. The long-run situation is less certain, especially if alternatives prove less effective for government-sponsored nematode containment programs. The extent of long-term impacts cannot be precisely determined, but should not be severe.

4. Peaches

EDB is used as a preplant nematocide on peaches. Primary target nematodes are ring, root-knot, lesion, and dagger nematodes. Prior to the suspension of DBCP, approximately 170,000 pounds of EDB active ingredient were used annually, enough material to treat about 2,000 acres of peaches. Almost all of this usage has been in the East, where over 13,000 acres of peaches are planted annually. Prior to the 1979 suspension, DBCP was used to treat an additional 8,325 acres annually. If the suspension of DBCP becomes a permanent cancellation, EDB would be the preferred chemical on these acres.

Registered alternatives to EDB for use in peach orchards are numerous, and include DBCP (temporarily suspended), DD, Telone, Vorlex, methyl bromide, zinophos, and chloropicrin. The major alternatives (DBCP, DD, and Telone) are equal in efficacy to EDB.

If DBCP use is allowed to continue on peaches, increased grower costs on the 2,000 acres currently treated with EDB would range between $20,300 and $118,180 annually ($10-$59 per acre), depending on the alternative chemical of choice (DBCP, DD, or Telone). However, if DBCP is permanently cancelled and EDB is assumed to be the preferred chemical on 10,325 acres, grower costs of an EDB cancellation would range from $378,700 to $610,100 annually (approximately $37 to $59 per acre) depending on the alternative chemical of choice (DD or Telone). At the industry level, the increased costs are not significant under either scenerio (with and without DBCP). No significant market or consumer impacts are expected if EDB becomes unavailable to peach growers.

5. Peanuts

About 17 percent of peanut acreage in the major U.S. peanut-producing regions is currently treated with EDB, resulting in annual EDB usage of approximately 4.2 million pounds of the active ingredient.

There are several registered alternatives to EDB for use on peanuts, although none are equally effective. The major liquid fumigant alternatives are Telone II and DD. Viable granular alternatives are Furadan, Dasanit, Mocap, Nemacur, and Temik, all of which are applied at planting. Each of thesealternatives is more expensive than EDB. It is estimated that substituting one of the several alternatives (choice of the particular alternative being dependent on many biological factors) for EDB would result in increased control costs to peanut growers of approximately $2.5 million per year.

More important than increased control costs is decreased value of production. If granular alternatives are used, yield losses of 6 percent are estimated due to reduced efficacy. If liquid formulations are used, yield losses will vary geographically from 7.5 to 9.0 percent. In the latter case, yield losses because of a required 10 to 14 day planting delay required to prevent phytotoxicity to the peanut plant. These yield losses would reduce producers' revenues by $11 million per year in addition to the $2.5 million per year increase in control costs. However, government price support programs are expected to prevent these losses from influencing consumer prices.

6. Cotton

EDB is registered for use throughout the cotton belt. An estimated 721,800 pounds were used in 1977, primarily to control the root-knot nematode. However, since that time, the suspension of DBCP may have increased usage to 1.6 million pounds annually. Telone II and DD remain as viable alternatives, and are equally effective under good soil conditions.

The only economic impact expected from cancellation of EDB would be an increase in cost of control, from $13.75 per acre with EDB to about $21.00 per acre with any of the alternatives. At an application rate of 2.5 gallons per acre (12.1 pounds a.i per gallon), an estimated 55,560 acres are treated annually with EDB. Use of substitutes for EDB on these acres would increase treatment costs by $435,700 per year. Compared to the approximate $3 billion value of the U.S. annual cotton crop, these increases are negligible. Accordingly, no measureable market or consumer impacts are projected.

7. Vegetables

Approximately 180,000 acres of various vegetables (broccoli, carrots, cauliflower, cucumbers, eggplant, lettuce, lima beans, melons, okra, potatoes, squash, strawberries, and tomatoes) are treated by preplant soil fumigation with EDB to control nematodes. Depending on the crop in question, EDB is applied at rates of 1.5 to 6.0 gallons per acre. An estimated 5.6 million pounds a.i. EDB are used annually.

Alternatives to EDB (Vorlex, DD, and Telone II) are considered equally effective. The loss of EDB on vegetables would result in increased pest control costs to vegetable producers of $3.8 million per year. There would be no loss in vegetable production due to the cancellation of EDB. Given a producer value of these vegetables of about $3 billion, the increased costs of the alternative fumigants would not have a significant impact on prices of these vegetables.

Producers of melon, lima beans, tomatoes and cucumbers would incur the largest impacts. This is due to the number of acres of these crops treated with EDB. On a per acre basis, the increased costs range from $6.88 for carrots to $28.90 for cucumbers.

Table 28 shows costs of alternatives to EDB on vegetable crops.

No significant market or consumer impacts are expected if EDB were not available for use on vegetables.

F. Minor Uses

1. Fumigation of Felled Logs

Several bark beetle species in the West attack coniferous trees and cause damage which can be reduced through the use of EDB. The alternatives are lindane and endosulfan. However, lindane is not considered a viable alternative because it is in RPAR review and the lindane PD 2/3 recommends its

Table 28

Alternative Nematocides Used to Replace EDB on Selected Vegetables, Cost of Materials and Changes in Nematode Control Cost, by Crop [a/]

Crop	With EDB	With alternative nematocides				Increase in nematode control costs	
		D-D	Vorlex	Telone II	Total	Total	Per Acre
	$1,000						
Broccoli	51	85	—	91	176	125	22.64
Carrots	381	285	—	202	487	106	6.88
Cauliflower	10	6	—	30	36	26	23.01
Cucumbers	201	269	420	143	832	631	28.85
Egg Plant	5	11	4	1	16	11	22.00
Lettuce	5	9	—	7	16	11	22.00
Lima Beans	248	462	—	492	954	706	23.57
Melons	330	724	—	406	1,130	800	23.11
Okra	59	129	67	27	223	164	25.57
Potatoes (white) [b/]							
A. Wash.Idaho	990	510	—	648	1,158	168	16.80
B.Other States	91	152	—	122	274	183	18.48
Potatoes (sweet)	214	291	—	—	291	77	11.85
Squash	11	6	10	26	42	31	25.83
Strawberries	15	16	—	35	51	36	22.50
Tomatoes	312	524	—	558	1,082	770	22.65
Totals	2,923	3,479	501	2,788	6,768	3,845	—

[a/] Application rates, material cost per gallon, and the alternative nematocides used were specified by the EDB Assessment Team based on product labels, State recommendations, efficiency of registered alternatives, and material costs per acre. The application rates and material cost per gallon are as follows:

Current control program:
EDB: 1.5 gallons per acre for lima beans; 4.5 gallons per acre for carrots; 6 gallons per acre for sweet potatoes and 1.67 gallons per acre for the remaining vegetables (12 pounds a.i. at $5.50 per gallon).
Terr-o-Cide: EDB 6 gallons per acre (8.43 pounds EDB and 7.03 pounds chloropicrin) at $16.50 per gallon.

Alternative control program:
D-D: 16 gallons per acre for sweet potatoes, and 11 gallons/A for remaining crops (10 pounds a.i.) at $2.80 per gallon.
Vorlex: 6 gallons per acre (11 pounds a.i.) at $8.00 per gallon.

cancellation for this use. Limited information indicates that endosulfan is less effective than EDB. Nonchemical controls, such as good silviculture practices, careful site selection, avoidance of monoculture, and thinning and removal of diseased or injured trees are also effective. However, during pest epidemics, chemical control may also be required.

Records show that in FY 1977, approximately 20,000 pounds of the active ingredient of EDB were used in Colorado and North Dakota only. Data for other areas are not available. At label rates, this is sufficient material to treat about 68,000 trees. EDB is used to treat trees that have already been attackedby bark beetles after the damaged tree has been cut. It is applied as an "open" log spray or under a plastic covering.

The extent to which EDB has been used for forestry purposes is not sufficient to appreciably affect commercial timber harvests. Rather, EDB is generally used where bark beetle damage may have aesthetic impacts to residential areas, wildlife habitats, or recreational areas. Such impacts are difficult to quantify, but typical residential lots suffering tree mortality from mountain pine beetle infestation could lose from $1,500-$3,000 in value.

Cost of control could be reduced by as much as $36,000 per year if endosulfan were to replace EDB; however, endosulfan may not be as effective as EDB.

2. Termite Control

EDB is the only pesticide registered by EPA as a fumigant for subterranean termite control. EDB is also state-registered in California for the control of drywood termites. Alternatives registered for control of subterranean species include aldrin, dieldrin, chlordane, heptachlor, pentachlorophenol (under RPAR review), and chlorpyrifos. For drywood species, registered alternatives include methyl bromide, sulfuryl fluoride, hydrogen cyanide, pentachlorophenol, and silica aerogel.

Estimates of EDB use vary from 5,000 to 12,000 gallons of formulation, or approximately 11,500 pounds to 27,600 pounds of the active ingredient per year. It is estimated that approximately 12,400 homes were treated with EDB for subterranean termite control in 1977. No data were available indicating units treated for drywood termite control.

Economic impact data regarding the use of EDB and alternative insecticides are limited; therefore, the magnitude of user, market, and consumer impacts cannot be precisely identified. Because the current use of EDB is small relative to other insecticides, overall impacts should be minor. However, certain homeowners, particularly in the southeastern and the southwestern U.S., who may experience difficulty in controlling subterranean termite infestations, could incur substantial losses. Because of the need to apply a fumigant into holes drilled in concrete foundations, there are no known chemical alternatives for homeowners in the Southeast and Southwest. The only known solution in this case is removal of the infested wood and rebuilding.

3. Fumigation of Stored Beehive Supers and Honeycombs

Honeycombs being stored between honey producing seasons are fumigated with EDB to control the larvae of the greater wax moth (GWM), which damage the waxcomb and bases held mounted on frames by hive supers.

Alternatives to EDB for this use are paradichlorobenzene (PDB) and carbon dioxide. In the North, cold weather is a natural control. Paradichlorobenzene is more practical to use than carbon dioxide, as the latter requires elaborate monitoring equipment to ensure efficacy and safety for the user. Paradichlorobenzene is somewhat less effective than EDB because it does not provide control of the egg stage of the GWM.

The use of PDB to replace EDB in the treatment of honeycombs will increase beekeeping costs by about $3.7 million annually. The cost per super treated will increase about 5 cents -- 4 cents with EDB versus 9 cents with PDB. Further, with PDB and CO_2 there would be 7 additional treatments needed per super.

Using the next best alternative, PDB, it is estimated that the volume of marketable honey would be reduced 20 percent in a super previously treated with EDB. This loss is due to decreased control of the GWM larvae which damage the honeycomb; in turn, the damaged honeycomb must be replaced with a fresh comb base prior to use in the hive during honey flow. Approximately one-third of all supers in the nation would be treated for the GWM using PDB in place of EDB. The total quantity of domestic honey would thus be reduced by 6.67 percent.

Annual honey production in the U.S. during 1975-77 averaged 191 million pounds. Based on a 6.67 percent reduction in honey production without EDB, the annual loss to beekeepers would be 12.7 million pounds, valued at $6.5 million.

To some extent, a production loss of this magnitude will result in higher consumer prices, thus shifting some of the impact of EDB cancellation from the producer to the consumer. The extent of this consumer price impact cannot be estimated.

In addition to these economic impacts, there will probably be some losses attributable to the reduced pollination service which bees provide. It is estimated that pollination services of honey bees are valued at $6 billion annually. Because the alternatives are not as effective as EDB, there will be some losses in pollination capacity resulting from the reduced number of colonies. It is not possible to estimate the impact on pollination which could result from the cancellation of EDB.

4. Fumigation of Stored Clothing and Furniture

Two products containing 5% EDB are registered for use in vault fumigation to control clothes moths attacking furs, woolen garments, rugs, carpets, linen, mohair, or upholstered furniture. The directions for one product state, "Use T-H Vault fumigant in a standard fumigation system, designed for evaporation of a liquid fumigant in a fur storage vault or de-mothing cabinet." This entails pouring the liquid fumigant into a small flat container within the vault and, depending upon the fumigant being used, placing the container near the ceiling or on the floor. The fumigant then evaporates and the gaseous fumes fill the vault to penetrate items being treated. Both product labels carry statements of caution regarding handling and operator protection and safety. Also, both products bear one or the other of the statements: "Not for household use" or "For pest control operators only."

Four alternatives to EDB were found for this use. The first is a mixture of carbon tetrachloride and ethylene dichloride in a ratio of 3 to 7. Since carbon tetrachloride is undergoing RPAR review, this alternative is not considered fully viable.

The second registered alternative is chloropicrin. It is a disagreeable material with which to work, but this property tends to discourage mishandling and exposure.

Methyl bromide is the third alternative. The three registered methyl bromide products also contain 0.25 to 2% chloropicrin, as an odor warning agent. For methyl bromide, the term "vault fumigation" would have to be interpreted liberally, because the labels cite barns, storage buildings, and other structures infested with these pests. Extreme care must be exercised before applying methyl bromide, because it reacts with a number of organic materials to produce foul-smelling odors. These materials include furs, feather pillows, leather goods, and a variety of woolens.

The final chemical registered for this site/pest combination is sulfuryl fluoride. Two products are registered, both containing 99% active ingredient. This chemical, like methyl bromide, is released as a gas through copper tubing from a pressure tank into the structure being fumigated. The economic impacts of EDB use on vault fumigation were not evaluated but are expected to be small.

5. *Fumigation of Quarantined Plants, Soil and Grass Sod*

The Japanese Beetle Domestic Quarantine program (7 CFR 301.48) requires the treatment of regulated articles (including such material as soil, balled plants and grass sod). Ethylene dibromide #440 (20% EDB), miscible ethylene dibromide #434 (2.5% EDB), and methyl bromide are authorized fumigants for these regulated articles to control the Japanese beetle. Because chlordane has been cancelled for all uses other than structural termite control and dipping the roots and tops of non-food use plants, it is limited only to some uses cited below. Therefore, methyl bromide is the single alternative used for comparison.

Labels for these EDB-containing products do not specify that use be restricted to certified applicators only, but do caution against inhaling, swallowing, skin contact, vapors near eyes, or contamination with feed and food stuffs.

Applications of EDB and methyl bromide for each of these articles are detailed below.

Grass sod: EDB #440 (20%) or #434 (miscible, 2.5%) is mixed at 20 cc EDB to 1 gallon of water, sprayed over the sod and left to stand undisturbed for 24 hours. This amounts to 20 lbs. of EDB per acre treated.

Methyl bromide is applied to cut, stacked, or rolled sod, under a tarp and left to stand for 3 hours. The average rate of treatment is 2.5 lbs a.i. per 1000 cubic feet or 60 pounds methyl bromide per acre under a tarpaulin.

Bare root plants: EDB #440 (20%) is mixed at 12 cc per gallon of water and the plant roots are soaked in the solution 24 hours. Methyl bromide application is 2.5 lbs/a.i. per 1000 cubic feet under a tarpaulin.

Plants Balled or in Containers: #440 EDB (20%) is mixed at 2 cc per gallon of water to be used as a dip or 2.5 cc per gallon of water to be poured on. Plants are then left undisturbed for 24 hours. There is also an injection method which is not ordinarily used at the present time. At this rate, 1.65 lbs. of EDB are used per 1000 cubic ft. of soil in balled and containerized plants. Methyl bromide is applied at a rate of 2.5 lbs. per 1000 cubic ft. under a tarpaulin.

Potting and bench soil: 50 cc of #440 is mixed in 3 gallons of water per cubic yard of soil (65 cc in 6 gallons of water for high organic soil). The soil is treated in 12 inch layers and soaked for 48 hours. Present annual usage amounts to less than 50 gallons of the formulation. (USDA, 1978). Methyl bromide is applied at a rate of 2.5 lbs. per 1000 cubic feet for 3 hours under a tarpaulin.

The economic impacts of the alternatives have not been evaluated. Fumigation chambers or technology are not generally available to nurserymen who are involved in this treatment on only an occasional basis.

IV. Identification of Regulatory Options

A. Introduction

As explained in Part I, FIFRA mandates the Agency to weigh the health risks and economic benefits of each use of a pesticide in order to achieve a balance between these competing considerations. In Chapters II and III, the Agency identified the risks posed by exposure to EDB and the benefits derived from each of its registered uses. To achieve a risk/benefit balance, the Agency has identified a number of regulatory options, and has evaluated each option for its impacts on both sides of the risk/benefit equation.

In addition, the Agency has evaluated the risks of alternative pesticideswhich have been identified as viable options for the various uses of EDB.

This section identifies the regulatory options available to the Agency to reduce the risks from the registered uses of EDB. The legal authorities for these options as provided in FIFRA are also discussed. In Chapter V of this document, each option will be evaluated for its impact on the risks and benefits of each registered use of EDB. These changes will then be compared to determine the most appropriate regulatory option for the specific registered use being examined.

B. Legal Basis for Options

FIFRA provides the Administrator with three broad legal courses of action for the registration of a pesticide. These are cancellation, continued registration without restrictions, and continued registration with restrictions.

Cancellation and continued registration without restrictions are opposite courses of action which hinge on a determination that a pesticide does or does not cause unreasonable adverse effects. To make this determination, the Administrator weighs the risks and benefits of each use of a pesticide. If the risks of a use outweigh the benefits, and the risks for that use cannot be lowered, the use may be cancelled. If the benefits of a use outweigh its risks, and any actions taken to reduce the risks result in a significant reduction in benefits, the registration of that use may continue. In the case of cancellation, the Administrator issues a notice of intent to cancel any or all registrations of a pesticide [FIFRA Section 6(b)(1)]. This cancellation notice becomes effective within 30 days, unless a registrant requests a hearing regarding its registrations. In the case of continued registration without restrictions, the Administrator may publish a final RPAR position document stating a rationale for choosing that course of action.

Between these polar alternatives of cancellation and continued registration without restrictions exists a whole range of possible regulatory actions. In fact, FIFRA requires the Administrator to "consider restricting a pesticide's use or uses as an alternative to cancellation...." [FIFRA Section 6(b)]. Although FIFRA does not specify what kinds of restrictions are to be examined, the Agency interprets this to mean amending the terms and conditions of registration in any fashion necessary to lower exposure (and consequently risk) to the point that benefits are greater than the risks, and the reduction in risks has not resulted in a significant reduction in benefits.

C. Data Gathering for Identification of Options

In the process of varying the terms and conditions of registration, the Agency can create an array of regulatory options intermediate to those of cancellation and continued registration without restriction. In order to facilitate the development of viable regulatory options, FIFRA provides the Agency with certain legal "tools" to be used in the process of gathering information on available options. The legal "tools" which FIFRA provides for developing intermediate options are:

1. Additional data

Under FIFRA section 3(c)(2)(B), the Administrator may require a registrant to submit any additional data necessary to maintain an existing registration. When reviewing an RPAR pesticide, the Agency may identify areas in its risk and benefit analyses where data are inadequate or totally lacking. The Administrator may then require a registrant to provide specific data within a certain time; if the registrant fails to comply, his registrations may be suspended.

2. Information-Gathering Hearings

If the Administrator is uncertain whether to cancel or restrict a pesticide, s/he may publish a notice of intent to hold a formal hearing to resolve the issue [FIFRA Section 6(b)(2)]. At the end of this hearing, the Administrator makes a decision based on the hearing record. As an alternative to a formal hearing, the Agency may conduct an informal hearing to gather information, [FIFRA Section 21(b)] and then use that information to propose a recommended decision.

D. Legal Options Available Under FIFRA

The following regulatory options are available to the Administrator under FIFRA to reduce the risks from the registered uses of a pesticide:

1. Classification for Restricted Use

FIFRA Section 3(d) enables the Administrator to restrict a pesticide's use(s) if such use(s) cause unreasonable adverse effects. This classification means that the pesticide may only be applied by or under the supervision of a certified applicator, one who is trained and approved by a state as competent to use restricted pesticides.

In classifying a pesticide for restricted use, the Administrator may also propose other restrictions specific to each use of the pesticide. The additional restrictions are aimed at reducing the risk to the general population and applicators. These other restrictions are discussed in Section E of this chapter.

2. Amend the Terms and Conditions of Registration

Under FIFRA Section 6(b)(1), the Administrator may offer the registrant the option of voluntarily amending the specific registered uses of a pesticide for which unreasonable adverse effects exist. Rather than to cancel all uses of the pesticide, the voluntary change in classification would permit the registration to be continued for certain uses which do not cause unreasonable adverse effects and it would be cancelled for those uses where unreasonable risks are present.

3. Labelling

FIFRA Section 3(c)(5) specifies that the label and labelling of a pesticide must comply with the requirements of FIFRA. That is, the label must not have use directions which result in unreasonable adverse effects. Consequently, the Agency may require a registrant to amend the label in order to keep the label in compliance with FIFRA. Examples of label changes include requiring protective clothing and/or respirators, warning applicators of the toxicological hazards of the pesticide, altering the application rates or methods, and other use or handling directions which are designed to reduce applicator exposures.

4. Establish or Re-evaluate Tolerances in Conjunction with FDA

Section 408 of the Food, Drug and Cosmetic Act requires that the Administrator, under recommendation from recognized experts qualified to evaluate pesticides, establish a tolerance for residues of a pesticide on raw agricultural commodities. Also, the Administrator may require that the registrants submit data in the form of a petition for tolerance according to the recommendations of an advisory committee.

The data required under Section 408 to establish a tolerance are:

(A) the name, chemical identity, and composition of the pesticide chemical;

(B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Should the Administrator cancel certain uses of a pesticide, s/he may revoke the established tolerance for that pesticide on the basis of the data supporting cancellation [40 CFR 180.32].

5. Cancel After a Specified Period of Time

If the Administrator determines that certain uses of a pesticide chemical cause unreasonable adverse effects, then s/he would issue a notice of intent to cancel those uses. If s/he also determines that there are no effective pesticide or nonchemical pest control methods currently available as effective alternatives to EDB, the Administrator could delay cancellation for a specified period of time to allow for development of alternatives. Such a decision would be implemented by issuing a notice of intent to cancel [FIFRA Section 6(b)(81)] and by conducting a formal hearing if requested.

In summary, FIFRA provides the Administrator with several legal authorities for regulating RPAR pesticides. With this legal foundation established, the Agency next must explore possible technical use restrictions (i.e., amendments to the terms and conditions of registration), and evaluate the extent to which these restrictions would reduce the risks of EDB.

E. Risk Reduction Measures for EDB

1. Use Restrictions for All Uses of EDB

This section presents the use restrictions which could apply to all uses of EDB. The restrictions listed here are intended to reduce exposure to applicators, other persons, and animals during and after fumigation. This section is intended only to present all of the potential options developed by the Agency, and not to indicate a decision to impose specific options. Sections following this one present additional restrictions specific to each use pattern. These additional restrictions are intended to reduce both applicator exposure and food residue exposures.

a. Classify EDB for Restricted Use

Due to the chronic hazards posed by EDB, the Agency could classify this pesticide for restricted use. Under this classification, only certified applicators or persons directly under their supervision would use EDB. A standard statement to this effect would appear on the label.

b. Protective Clothing

To prevent dermal contact with EDB, applicators could be required to wear boot covers, disposable gloves and an apron during transfer of the pesticide (i.e., pouring), during calibration or maintenance of application equipment, or during clean-up of spills. These protective articles must be made of a material resistant to EDB penetration. Butyl rubber is recommended for use in gloves. Nitrile and polyethylene, while less resistent, are sufficient for use in aprons, coveralls and boot covers where close body contact does not occur. Articles made of natural rubber or leather should not be used. Contaminated clothing should be removed immediately and exposed skin washed with soap and water. Gloves and boot covers would be thrown away immediately if contaminated, or after each use (not to exceed one hour) in any event. Other clothing would be commercially laundered daily, or aired for at least 24 hours. All of these requirements would appear on the label.

c. Respirator

A respirator could be required to be worn at all times during application and when reentering the treated site throughout the specified reentry period. A full-face black canister gas mask approved by NIOSH/MSHA for removing organic vapors could be used. Applicators would be trained to properly wear, maintain, and store a respirator. The black canister or charcoal filter is to be replaces after each day or use. All of these requirements would appear on the label.

d. Reentry Period

Before application, signs would be required to be posted at entrances to the treated area (i.e., treated field or building) bearing the signal word "DANGER," the product name, date of treatment, treatment period (if applicable), the date when reentry is allowed, and what protective equipment is required. The sign would remain posted during application and throughout the period before reentry is allowed. The label would also contain this information. Sample warning statement might read:

FOR OUTDOOR FUMIGATION:

DANGER

> SOIL FUMIGATED WITH (PRODUCT NAME) ON (DATE). DO NOT REENTER TREATED AREA UNTIL (REENTRY DATE) OR*UNTIL EDB AIR LEVEL IS LESS THAN 0.4 PPM . WEAR A FULL FACE BLACK CANISTER RESPIRATOR IF YOU MUST REENTER THIS AREA BEFORE THE POSTED REENTRY INTERVAL.

FOR INDOOR (SPACE) FUMIGATION:

DANGER

> PREMISES FUMIGATED WITH (PRODUCT NAME) ON (DATE). TREAMENT PERIOD LASTS UTIL (DATE). WEAR A FULL FACE, BLACK CANISTER RESPIRATOR BEFORE REENTERING PREMISES. AFTER TREATMENT PERIOD, OPEN ALL WINDOWS, DOORS AND VENTS. REENTRY WITHOUT A RESPIRATOR IS ONLY PERMITTED AFTER 24 HOURS OF AERATION OR WHEN EDB AIR LEVEL IS BELOW 0.4 PPM.*

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* 0.4 ppm is the lowest level at which an IR detector alarm can sense the presence of EDB. These detectors are available from the Foxboro Company, Wilkes Infrared Center, S. Norwalk, CT.

e. Warning of Chronic Risks

The label would indicate that EDB poses a risk of cancer and mutagenic effects to humans in addition to the acute effects already described on the label. A sample sentence is:

> "EDB HAS CAUSED CANCER, MUTAGENIC EFFECTS AND REPRDUCTIVED DISORDERS IN LABORATORY ANIMAL TESTS AND MAY PRESENT THESE HEALTH RISKS TO HUMANS".

f. Other Safety Precautions

The label would also include statements expressing the following requirements:

- Fumigation may take place only when personnel will not be in the area (i.e., treated field or building) during the treatment period and the reentry period. Humans and animals must be vacated from treatment area before fumigation;
- EDB may not be used or stored in domestic dwellings;
- Soap and water must be available for washing skin or flushing eyes in case of contact with EDB;
- Hands must be washed before eating or smoking;
- Transferring activities (i.e., pouring) must be conducted outdoors, unless a closed system of transfer is used;
- Spills must be cleaned up immediately. If a spill is on soil, cover with six inches of soil. If a spill occurs on other surfaces, remove EDB with an EPA-approved cleaning agent;
- Pesticide containers are disposed of by either burying in a State-approved pesticide disposal site or by returning them to a container reprocessor;
- Containers or equipment made of aluminum, magnesium, or their alloys must not be used, because EDB will corrode them.

2. Additional Requirements for Soil Fumigation Uses

Reentry Period. Reentry without full-face, black canister respirator into treated area will not be permitted until 24 hours after fumigation is completed. This information would appear on the label and on warning signs posted around treated areas. This requirement would supersede the minimum use restriction mentioned previously in that it proposes a specific reentry time interval. The reentry interval is based on data indicating that EDB level are below the level of detection at 24 hrs. after fumigation.

3. Additional Requirements for Stored Grain Fumigation

a. Restrictions for Reducing Applicator and Reentry Exposure

1) Protective Clothing

EDB-resistant gloves (butyl rubber), boot covers and apron (butyl rubber, nitrile, or polyethylene) would be required at all times during fumigation.

This requirement would supersede the minimum use restriction of wearing protective clothing only during mixing and loading, etc. The label would describe this additional requirement.

2) Use Directions

Before fumigation, all leaks and vents in the grain storage structure (e.g., bins, flats, elevators, boxcars or other storage facilities) would be required to be sealed with masking tape, caulking or plastic. Humans would be vacated from the structure to be treated. Only devices which apply the fumigant quickly, evenly and with minimal vaporization would be permitted (such as a sprinkling can without a nozzle or a coarse stream power sprayer). After fumigation is completed, the treated structure would be sealed and all entrances locked. The label would describe these requirements.

3) Reentry Period

After the treatment period has elapsed, a respirator could be required to be worn upon reentry, all doors and windows opened, and aeration systems activated (if available). Reentry without a respirator would be permitted only after 24 hours of aeration or until an IR detector indicated a concentration of EDB in air no more than 0.4 ppm. The label and posted warning signs would bear this information.

4) Placarding Treated Grain

Treated grain transported to another location would be placarded with a sign indicating the date of last treatment. This sign could be removed at the grain's destination. The purpose of this use restriction is to warn grain inspectors and other workers of the previous use of a fumigant in a particular grain shipment. The label would include this restriction. As a further safety measure, grain inspectors would use an IR detector to determine whether transported grain contained levels of EDB gas in excess of 0.4 ppm. If levels were to exceed 0.4 ppm, grain would be held in quarantine at the elevator until EDB gas measurements were below the 0.4 ppm level.

b. Restrictions for Reducing Food Residues

1) Require a Holding Period for Treated Grain

EDB slowly dissipates from treated grain held in storage. To allow EDB residues to dissipate, the Agency will consider requiring holding periods of 30, 60, or 90 days for treated grain. If a holding period were imposed, it would be stated on the label and on the placard that accompanied the transported grain. Tolerances would be established, or changes in labelling would be made to enforce this requirement.

2) Prohibit "Off-Farm" Fumigations (Country Elevators, Terminal Elevators, Boxcars, Trucks, ,Mill Storage, etc.).

Because "off-farm" use of EDB contributes about 3/4 of the dietary risk from grain, the Agency could prohibit these uses. The only uses on grain which would be permitted under this restriction would be "on-farm" fumigation of grain stored in warehouses, bins, or under tarpaulins. If this restriction were imposed, it would be required to appear on the label. Tolerances would be revised or changes in labelling could be imposed to enforce this measure.

3) Prohibit "Off-Farm" Use and Prohibit"On-Farm" Treated Grain from Being Used for Human Consumption

To eliminate direct dietary exposures of EDB through treated grain, the Agency will consider prohibiting the use of treated grain for direct human consumption. To ensure that this restriction is followed, registrants would be required to add an FDA-approved dye to their products; grain treated with EDB would then be discolored and identifiable as illegal for human consumption. This requirement would have to appear on the label. Tolerances would be revised or changes in labelling could be imposed to enforce this measure.

4. Additional Requirements for Spot Treatment of Milling and Cereal-Handling Machinery

a. Use Restrictions for Reducing Applicator and Reentry Exposure

1) Protective Clothing

EDB-resistant gloves (butyl rubber), boot covers and apron (butyl rubber, nitrile, or polyethylene) would be worn at all times. The label would state this.

2) Use Directions

Before fumigation, milling equipment would be run dry to minimize the amounts of flour and grain parts left in the machinery. Persons not involved with the fumigation would be vacated from the building. Only a "closed system" hand-held applicator gun or an automatic dispensing system would be used to apply EDB. Open pouring or pouring into bottles would be prohibited. After completing fumigation, all windows, doors, vents and entrances would be locked shut. These requirements would appear on the label.

3) Reentry Period

After the 24 hour treatment period, a respirator would be required to be worn to reenter the building. All doors, windows and vents would be opened at this time. Before anyone could reenter the treated building without a respirator, the premises would be aerated 24 hours or until an IR detector showed that EDB air levels are below 0.4 ppm. The label and posted warning signs would bear this information.

b. Restriction for Reducing Food Residues

Prohibit a Quantity of Contaminated Flour from Being Used for Human Consumption. After spot treatment a mill could require several hours to start producing flour of acceptable quality. This first batch of flour is normally separated and then slowly fed back into the flour stream. Because a significant portion of the EDB residues resulting from spot treatment occur in this start-up batch, the Agency would require that the batch of flour be discarded. This requirement would appear on the label.

5. Additional Requirements for Post-Harvest Fumigation of Citrus and Tropical Fruits

a. Engineering and Operational Changes for Fumigation Facilities.

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) regulates all fumigation centers in the U.S. and two centers in Mexico. APHIS regulations and its treatment manual would be revised so that each fumigation center meets a standard of a maximum permissible level of EDB concentration in air of 0.4 ppm (15 min. avg.). To meet this standard, APHIS could implement any of the following risk reduction measures to achieve the air standard in addition to those which appear on the label (See Section IV. E. above):

-Closed dispensing system (EDB-resistant tubing with soldered connections), including an air coupling (with which to purge the line before opening it), and a pressure relief valve. Valves would be designed for handling EDB.

-Air monitoring device with an IR detector connected to an alarm and calibrated to be triggered if the EDB air levels in the hallway exceed 0.4 ppm.

-Ventilation system would be adjusted so that there is greater pressure in the hallway than in the fumigation chamber.

-Training of applicators in all aspects of fumigation procedures, protective equipment, safety precautions and emergency plans.

-Testing of fumigation chambers for leaks before the USDA inspector approves a fumigation permit.

-Restarting exhaust fan after opening chamber door to move EDB vapors away from workers.

-Monitoring of personnel to detect EDB exposure levels on a scheduled basis.

-Posted operating instructions and emergency procedures.

b. Requirements for Warehouses Holding Treated Commodities.

APHIS is responsible for reducing exposures that result from treated fruit as it is transported or stored. Because high exposures have been detected during warehouse workers' handling of treated fruit, APHIS could require these warehouse facilities to meet the standard of 0.4 ppm EDB in air. This would involve:

-Monitoring of personnel to detect EDB exposure levels on a scheduled basis.

-Installation of ventilation systems in warehouses adequate to ensure that exposure does not exceed 0.4 ppm.

-Installation of detection/alarm devices in warehouses calibrated for 0.4 ppm.

-Requiring full-face, black canister respirators for all personnel who are exposed to EDB air levels higher than 0.4 ppm. (For instance, the "stickmen" who unload treated citrus from trucks would have to wear a respirator unless the cardboard containers are eliminated.)

-Replacement of cardboard citrus boxes with a bulk loading system made of a non-EDB-absorbent material. (This requirement would be optional. However, a bulk loading system may reduce exposure to less than 0.4 ppm and thereby eliminate the need for workers to wear respirators.)

-Training of all warehouse personnel about hazards of EDB, methods for reducing exposure, and emergency procedures.

-Signs would be posted in warehouses stating:

WARNING - FUMIGATED FRUIT MAY EMIT HARMFUL ETHYLENE DIBROMIDE VAPORS. IF AIR LEVELS BECOME HAZARDOUS AND ALARM SOUNDS, PUT ON FULL-FACE BLACK CANISTER RESPIRATOR IMMEDIATELY.

c. Restriction for Reducing Food Residues

Require treated fruit to be stored for a specific period. One approach to reducing EDB residues in treated commodities is to lengthen the treatment-to-market interval by requiring treated fruit to be stored for a certain period after treatment. Based on the available data the Agency has estimated a degradation formula for EDB residues in treated fruit. Using this formula for citrus, EDB residues are estimated to decrease from 8 ppm to 1.42 ppm during a six-day treatment-to-market interval. If this treatment-to-market interval were lengthened, EDB residues could be further reduced. To explore the feasibility of this approach the Agency could require APHIS to hold treated fruit from commerce for a certain time period. This requirement would be stated on the label.

6. Additional Requirements for Fumigation of Beehive Supers

a. Use Restriction for Reducing Applicator and Reentry Exposure

1) Protective Clothing

The label would state that EDB-resistant gloves (butyl rubber), boot covers and apron (butyl rubber, nitrile or polyethylene) would be worn at all times.

2) Use Directions

Hives and/or combs (supers) would be placed in a gas-tight room or under a gas-tight covering such as a polyethylene tarpaulin held down with sand-filled "snakes". All windows, doors and vents would be sealed. All persons not involved with the fumigation would be vacated from the building. The label would state these directions.

3) Reentry Period

Following the treatment period, a full-face black canister respirator would be worn when reentering. All doors, windows and vents must be opened at this time. Aeration for 24 hours or until EDB air levels are less than 0.4 ppm, measured by IR detector, shall be required before reentry is permitted. The label and warning signs would contain this information.

b. Restriction to Avoid Food Residues

Limit fumigation to beehive supers that are clean and in storage. To avoid possible contamination of honey or honeycombs, the label would prohibit treatments other than on clean supers in storage. This restriction is in accordance with current practice.

7. Additional Requirements for Vault Fumigation of Stored Clothing.

a. Use Restrictions for Reducing Applicator and Reentry Exposure

1) Commercial Use Only

Vault fumigation would be conducted only by certified commercial applicators in commercial clothing storage vaults. The label would state this.

2) Use Directions

Before fumigation all doors and leaks in the vault would be sealed. All persons not involved with the fumigation would be vacated from the building. This requirement would appear on the label.

3) Reentry Period

Following the treatment period, a full-face, black canister respirator would be required to be worn during reentry. All doors and vents in the treatment area and connected buildings would be opened at this time. Premises would be aerated 24 hours or until the EDB air level is less than 0.4 ppm increased by an IR detector, before reentry is allowed. The label and posted warning signs would contain this information.

8. Additional Requirements for Fumigation of Subterranean and Drywood Termites

a. Use Restrictions for Reducing Applicator and Reentry Exposure

1) Certified Applicators

Fumigation would be carried out only by certified commercial applicators.

2) Protective Clothing

EDB-resistant gloves (butyl rubber), boot covers and apron (butyl rubber, nitrile, or polyethylene) would be required at all times. The label would state this.

3) Use Directions for Drywood Termites

Persons not involved with the fumigation would be required to be vacated from premises. Holes of size and spacing specified by the registrant should be drilled and the recommended dosage of EDB injected into these holes using a calibrated syringe or like device. The label would state these requirements.

4) Use Directions for Subterranean Termites

Persons not involved with the fumigation would be vacated from premises before fumigation and subsequent aeration. Use would not be permitted under slabs which contain air ducts, electrical conduits, or the like. Recommended dosage would be injected through holes drilled in concrete slabs which support infested structures. All holes would be plugged temporarily to prevent the escape of EDB during treatment, and would be sealed permanently immediately after treatment. The label would state these requirements.

5) Reentry Period

During and after fumigation all doors, windows and vents in the treatment area and connected buildings would be opened. Premises would be aerated 24 hours or until EDB air levels are below 0.4 ppm before reentry would be permitted. The label and posted signs would contain this information.

9. Additional Restrictions for Fumigation of Bark Beetle

a. Use Restrictions for Reducing Applicator and Reentry Exposure

1) Protective Clothing

EDB-resistant gloves (butyl rubber), boot covers and apron (butyl rubber, nitrile or polyethylene) would be required at all times. The label will state this.

2) Use Directions

EDB would only be applied to infested, felled logs by spraying recommended dosage onto stacked logs, immediately covering the stack with heavy plastic, and sealing this cover with sand snakes. Signs would be posted on the treated stacks stating when the cover could be removed. Spraying logs in the open without an approved covering would be prohibited.

10. Additional Restrictions for Fumigation of Japanese Beetle Under USDA Quarantine Program

a. Restrictions for Reducing Applicator and Reentry Exposure

Under the authority of the Organic Act (7 U.S.C. 147a), the APHIS program of USDA has established a Japanese beetle quarantine program which requires fumigation of certain regulated articles (such as infested plants, grasses or soil) before they can be shipped out of a quarantined area. The APHIS Japanese Beetle Program Manual specifies the approved pesticides and treatment methods. A review of this manual indicates that it could be revised to include the aforementioned minimal use requirements. Further, a review of the two currently registered labels for this use (registration numbers 1681-6 and 3743-263) shows that these labels could be upgraded to describe all the use restrictions and directions for this use pattern. Following are the additional use restrictions or revisions in the APHIS Manual developed by the EPA for each regulated article:

1) Grass Sod

Treated sod would be required to be covered with a heavy plastic or tarp during the treatment period to ensure an efficacious treatment and to minimize air exposures. The tarp would be required to be aired before re-use.

2) Bareroot Plants

The proper method for disposing of the used EDB-water mixture would be specified.

3) Balled or Containerized Plants

The "enclosed place" into which plants are placed after treatment would be posted with signs indicating the minimal reentry information described previously. Proper disposal methods would be described.

4) Potting and Bench Soil

Soil would be covered with plastic or heavy tarp for the duration of the treatment period.

5) Beds and Other Uses

Soil would be covered with plastic or heavy tarp for the duration of the treatment period.

6) For All Above Uses

The APHIS Manual states for balled or containerized plants that treatment is approved only when beetle grubs (larvae) are present. This requirement would be imposed for all regulated articles to avoid unnecessary applications.

V. SELECTION OF REGULATORY OPTIONS

A. Introduction

The purpose of this chapter is to determine the most appropriate regulatory options the Agency should propose for each registered use of EDB. To accomplish this, the risks to human health and the environment for each registered use are systematically compared with the benefits which result from that registered use. If this comparison demonstrates that "unreasonable adverse effects" to man or the environment exist for particular uses, then specific regulatory options are developed to reduce the risks for each of those uses. The Agency then evaluates the extent to which these regulatory options will change the risks and benefits of each use of EDB. Finally, by comparing the changes in the risks and benefits the Agency selects and proposes the most appropriate regulatory measure for each use of EDB.

In previous chapters of this document, the Agency has evaluated both the risks and the benefits which exist as a result of the currently registered use practices of EDB. In addition, the Agency has summarized the regulatory options which are available under FIFRA.

As discussed in Chapter II of this document, the Agency has examined all of the available health studies on EDB. These studies include investigations of possible carcinogenicity, mutagenicity, and reproductive disorders. After a careful review and evaluation of these studies, qualified Agency scientists and outside consultants have reached several conclusions regarding the possible hazards which may result from exposure to EDB.

Based on the accumulation of evidence, the Agency considers EDB to be a potent animal carcinogen and a probable human carcinogen. Because the pesticidal uses of EDB result in human exposure during application, through contamination of some foods during application, and during transport of treated commodities, the Agency concludes that EDB poses a risk of cancer to humans. The Agency also concludes that EDB causes reproductive disorders in bulls, rats and chickens, suggesting that repeated exposure to EDB may cause reproductive disorders in humans. Finally, the Agency concludes that adequate multitest evidence exists to demonstrate that EDB also causes mutagenic effects in several organisms. This evidence indicates that exposure to EDB poses a potential risk of genetic damage to man. Collectively, these three conclusions confirm qualitatively that human exposure to EDB poses substantial risks to the public health.

The Agency has quantitatively estimated the cancer risks to the public which exist due to current registered use practices. Animal toxicity data and the human exposure estimates were used to evaluate the lifetime probability of EDB-induced cancers to the general population and to occupationally-exposed workers. Probability estimates, based on total dietary exposure resulting from residues persisting in EDB-fumigated commodities, range from approximately 10^{-6} to 10^{-4}. Applicator risk estimates range from 10^{-5} for soil fumigation operators to 0.4 for some persons involved in the fumigation ofcitrus.

The Agency has determined that human exposures to EDB also pose a risk of mutagenic effects and reproductive disorders to exposed individuals. The Agency has not quantitified the risk of mutagenic damage to exposed individuals, but has concluded that these risks exist and must be taken into consideration in determining the most appropriate regulatory actions. Based on the NOEL for reproductive disorders observed in rats (as well as the reproductive disorders observed in bulls) and based on the applicator exposure levels, the Agency has also determined that an adequate margin of safety does not exist. Although the Agency does not plan to perform a quantitative risk assessment for reproductive disorders, it will propose regulatory options that should provide an adequate margin of safety by significantly reducing exposure.

Benefits resulting from the use of EDB, summarized in Chapter 4 of this document, are estimated to be approximately 60 million dollars per year. Of the estimated fifteen million pounds of EDB used annually, over eleven million pounds are used for soil fumigation. However, the largest economic benefits of EDB use do not result from its use as a soil fumigant but result from a significantly lower volume use - the USDA APHIS quarantine program. This program requires that in certain geographic areas citrus and certain other commodities be fumigated with EDB prior to transport in order to prevent the spread of fruit flies into geographic regions where they are not established. While this program accounts for less than one percent of the annual EDB usage, it can account for over 30% of the benefits of EDB, an estimated 24 million dollars annually.

It is for reasons such as this that each major use category is systematically analyzed in the following pages using these and significant factors. For a given use category, the risks and benefits are reviewed and the data gaps identified. The significant human health risks are then weighed against the corresponding benefits and a judgment is made as to whether or not the risks outweighed the benefits. If regulatory actions are required to reduce these risks, an analysis is then made of the extent to which each available regulatory action might reduce the risks. The most reasonable regulatory measure is identified and proposed for that use category.

B. Fumigation of Stored Grains

1. Summary of Risks and Benefits

The Agency has determined that the general population, grain fumigation applicators, and individuals handling EDB-fumigated grains are at risk to health hazards as a result of exposure to EDB. The risks include cancer, mutagenic damage, and reproductive disorders. As discussed in Chapter II, the Agency has concluded that residues of EDB persist in flour, baked breads, and other baked flour products made from wheat fumigated with EDB. The range of expected residues which the Agency has determined occur in bread baked from this flour vary from 0.07 ppb to 38 ppb. Based on these residue levels, the Agency has estimated that the lifetime risks of EDB-induced cancer to the average U.S. citizen on a typical diet vary from approximately 10^{-6} to 10^{-4} for this registered use. Although the Agency has not quantitatively estimated the public's dietary risk of mutagenic damage and reproductive disorders, it has concluded that these combined risks warrant consideration of additional regulatory actions.

The Agency has no monitoring data on exposure to EDB for individuals who fumigate stored grains. However, based on available exposure data from similar use practices for other grain fumigants, the Agency has concluded that grain fumigant applicators are exposed to EDB through dermal contact and the inhalation of EDB vapors. Mixing, loading, use, and storage of EDB-containing grain fumigants can expose applicators and individuals in the immediate vicinity to EDB vapors. Commonly occurring spills of these fumigants on skin or clothing also result in dermal contact for applicators. As a result of these exposures, about 50,000 to 60,000 applicators and "non-involved" persons are potentially at risk to the health hazards of EDB.

In addition to the above risks, persons involved in the transport or handling of EDB-fumigated grains as they move through commerce (dock workers, grain inspectors, etc.)are potentially at risk to the health hazards of EDB. These risks result in people being exposed to vapors which have slowly dissipated from treated grains and which have been trapped in storage or transport systems. The Agency has no exposure data for this occurrence and has not estimated the number of people exposed in these situations. The Agency has determined that the health risks resulting from these exposures, should be considered in the selection of an appropriate regulatory action for this use.

Bystanders in the immediate area of use or transfer of EDB grain storage fumigants can also be exposed to EDB vapors. The Agency has not evaluated the exposure to these individuals in its quantitative risk estimates because of a lack of needed data. There are no estimates of the number of persons exposed, but the Agency recognizes that such exposure can occur and would be attended by health risks which should be considered in the development of a proposed regulatory position.

The Agency has evaluated the economic benefits of grain fumigation with EDB and has determined that on a national basis there would be no adverse economic impacts if EDB were cancelled; in fact, users would save money by using alternative pesticides. As discussed in Chapter III, EPA has determined that certain available alternative fumigants, if used properly, are more economical and that, on a national basis, farmers would save approximately 0.5 to 2 million dollars by using them. These alternatives, which will be examined in detail later in this section, are aluminum phosphide and a mixture of carbon tetrachloride and carbon disulfide.

These savings tend to obscure the fact that under certain conditions there are advantages in using EDB. Grain storage facilities, which allow fumigant vapors to dissipate easily because the storage facility is not well-sealed, may be better suited to EDB due to its characteristic persistence. However, the Agency has concluded that, in most cases, the alternatives will be more economical.

If EDB were cancelled, the most likely substitutes would be a mixture of carbon tetrachloride and carbon disulfide at on-farm storage facilities, and aluminium phosphide at off-farm storage centers. Because on-farm and off-farm facilities vary widely in airtightness, the substitutes also vary -- the tighter the facility, the more likely it is that the substitute would be aluminum phosphide. This grain fumigant is less costly but requires a well-sealed storage facility and a longer exposure period to be effective.

2. Risk/Benefit Analysis

Based on the above risk and benefit information, the Agency has concluded that the risks exceed the benefits for EDB fumigation of stored grains. Thus, risks of unreasonable adverse effects to the public health exist and will continue to exist unless regulatory actions are implemented to reduce oreliminate these risks. This conclusion is based mainly on potential dietary risks and the estimated negative economic benefits. It is supported by the potential health risks to grain fumigant applicators, individuals who handle EDB-fumigated grains, and non-applicators who may be exposed to EDB vapors during storage, transfer, or use.

Accordingly, the Agency has evaluated several regulatory options which might reduce these risks. Table 29 displays the impacts which each regulatory option would have on human health risks resulting from exposures to EDB, the health risks of the likely substitutes for this use of EDB, and the expected economic impacts.

All actions short of immediate cancellation would result in continued dietary risks. Options 2 and 3, "Classify for Restricted Use" and "Restricted Use Classification Plus Changes in the Terms and Conditions of Registration" would result in some reduction in applicator and dietary risks because some EDB users might voluntarily switch to alternatives. However, only immediate cancellation would eliminate all EDB dietary and inhalation risks. Because unreasonable dietary effects continue to exist for all options less restrictive than immediate cancellation, the Agency has concluded that immediate cancellation of this registered use of EDB is necessary. Immediate cancellation is further supported by the availability of alternative fumigants which are less expensive and which the Agency considers will pose less risk to applicators and the public when compared to EDB.

To reach determinations about the risks of the alternatives, available health effects-related studies on these chemicals were reviewed with these results:

Use of aluminum phosphide in not expected to result in unreasonable risks to applicators or the general public. Aluminum phosphide has an established tolerance for many food products including grains. This chemical rapidly reacts with water in air resulting in the release of phosphine gas and a residue of aluminum hydroxide. It is this gas which actually destroys insect infestation. Because phosphine is a highly reactive and fugitive gas, residues on commodities or treated materials are not expected. Phosphine is acutely toxic and poses a risk to unprotected applicators. If the precautions specified on the label are followed explicity, applicators, should be adequately protected. Aluminum hydroxide, a common ingredient in antacids, does not appear to pose a health hazard, as determined by an FDA review of toxicology data.

Carbon disulfide (CS_2) is an acutely toxic, highly flammable and penetrative liquid. It is formulated in a mixture with carbon tetrachloride and other fumigants to reduce its flammability. Adequate toxicological data are not available to determine if carbon disulfide poses chronic hazards to humans. Likewise, no studies have been conducted to determine whether residues of CS_2 might occur in food. Though CS_2 is exempt from tolerances for grains because residues were not expected to occur in food or feed, the Agency considers it prudent and is initiating a study to determine if any residues of CS_2 can be detected in grain or flour. If residues are found, registrants of CS_2 may be required to submit chronic feeding studies.

The third major alternative pesticide is carbon tetrachloride. Now under RPAR review, CCl_4 has been presumed to present a risk to humans of cancer, chronic liver effects and chronic kidney effects. CCl_4 is also suspected of inducing mutagenic and teratogenic effects in laboratory tests.

Table 29 Impacts of Regulatory Options on Stored Grains

Regulatory Option	EDB Human Health Risks Exposure Route	 Risks	Risk of Substitutes Human/Environmental	Economic Impacts Users	 Consumers	Comments
1. Continued Registration	Inhalation, Dermal Dietary	See Tables 18 and 20 for cancer risks and discussion in Chapter II for other possible risks	Not applicable	None	None	Unreasonable dietary, dermal and inhalation risks continue
2. Classify for Restricted Use and require: A. Protective Equipment B. Reentry Period C. Placarding	Many users will voluntarily switch to alternatives rather than follow this restriction. Some users will continue with EDB.	Reduced risks to applicators. Dietary risks are reduced only if users switch to alternative fumigants.	Carbon Disulfide has data gap for chronic hazard (data to be required if EPA study finds residues in bread). Aluminum phosphide is acutely toxic but presents no particular hazard. Carbon tetrachloride is carcinogenic but exposure to this would not increase.	Not Analyzed	None	Unreasonable dietary risk to consumers and dermal and inhalation risks to non-applicators continue.
3. Option 2 plus any of the following changes in terms and conditions of registration A. Holding period B. Cancel on-farm EDB use C. Cancel off-farm EDB use D. Prohibit treated grain from going to human consumption	Same as Option 1.	Dietary risks may be reduced, but monitoring and enforcing these terms and conditions would be difficult.	Same as Option 2 Dietary risks may be reduced, but monitoring and enforcing these terms and conditions would be difficult.	Unknown. (Analysis was not done due to questions of enforceability).	None	Dietary risks may not be reduced to acceptable levels because the Agency is not confident that changes in terms and conditions would be followed or enforceable
4. Cancel after 5 years and implement Option 3 in the interim.	Same as Option 1	Dietary and inhalation risks would continue for 5 yrs.	Not applicable	None	None	Would allow existing stocks to be used.
5. Cancel immediately	None	EDB risks eliminated	Same as Option 2	Users will save $0.5 to $2.26 million.	Negligible	Additional residue data being developed for substitutes by the Agency. Chronic exposure studies may be required for CS_2 if there is exposure.

However, the cancellation of EDB is not expected to increase the health risks of CCl_4, because exposures to CCl_4 are not expected. The EDB mixture which is applied to grain, is formulated with CCl_4 and other liquid fumigants. The concentration of CCl_4 in these mixtures usually ranges between 70% and 90%. If EDB is cancelled, the predominant substitute is a mixture of 80% CCl_4 and 20% CS_2. Thus, roughly the same amount of CCl_4 is contained in the substitute mixtures. As a result, exposure to CCl_4 would not be expected to increase.

In summary, from the available information, the Agency concludes that, aluminum phosphide and carbon disulfide used according to labeled safety precautions, will not pose the range or magnitude of adverse health effects to users and to the public that the use of EDB poses. Once cancellation is effective, the Agency will initiate action to revoke the current exemption for grain from tolerances for EDB.

The Agency must act to reduce the unreasonable risks posed by EDB. Cancellation is the most effective and viable option in light of the high risks of EDB and the fact that the alternative fumigants, which are less expensive, are just as efficacious and will not pose the range or magnitude of adverse health effects to users or the public as demonstrated for EDB. This decision is enhanced by the recent development of carbon dioxide, nitrogen and combustion product gas as effective means of controlling pests in stored grain. If these gasous insecticides are exempted from tolerances and prove to be technically and economically feasible, they will be additional alternatives to EDB.

C. QUARANTINE FUMIGATION

1. Summary of Risks and Benefits

As discussed in Chapter II, over 99% of the EDB used for quarantine purposes in 1977 was applied to citrus and tropical fruits (85,000 lbs.) and the remaining amount (300 lbs.) was applied to miscellaneous fruits and vegetables. The Agency has determined that both the risks to human health and the economic benefits which result from this registered use may be substantial. The Agency is concerned that the estimated benefits may substantially overstate the economic value which results from current use practices for this registration. This issue and the fact that there are currently no registered chemical or approved nonchemical alternatives for this use have complicated the Agency's decision as to what regulatory action to propose for the use of EDB in quarantine fumigation.

In Chapter II, the Agency established that significant human health risks are present as a result of current EDB use practices in quarantine fumigation programs. These include risks to the health of the general public through exposures to EDB residues persisting in treated commodities, and health risks to occupationally-exposed individuals, including those working at or around EDB fumigation centers and those working in warehouses where fumigated commodities are temporarily stored. The health risks are cancer, mutagenic effects, and reproductive disorders.

The Agency has quantitatively estimated the lifetime cancer risks to the general public and has established that significant cancer risks result from current practices at quarantine fumigation centers. The residue estimates forming the basis of estimated risks are supported by chemical analyses of EDB residues which were found in commodities obtained from retail grocery stores.

As discussed in Chapter II, the Agency has determined that the lifetime risks of EDB-induced cancer to the general public range from approximately 10^{-4} for citrus to 10^{-5} for tropical fruits.

The Agency has also determined the lifetime risks of cancer for persons occupationally exposed, including fumigation center employees, truckers involved in the transport of fumigated commodities, and persons involved with the movement and handling of fumigated commodities into and out of warehouses. As discussed in Chapter II, the Agency has estimated the cancer risks to fumigation center employees to vary from approximately 10^{-3} to 10^{-2}, to warehouse workers from approximately 0.1 to 0.4, to outdoor operators of approximately 10^{-3}, and to truckers of approximately 10^{-3}. These cancer risks are among the highest risks the Agency has ever confronted.

In addition to these quantified risks, the Agency has also concluded that adequate evidence exists to demonstrate that EDB causes mutagenic effects in several organisms and reproductive disorders in exposed animals. Though the numerical range of the risks of these health hazards is not available, the Agency has concluded qualitatively that humans exposed to EDB are also at risk to genetic damage and reproductive disorders. These additional risks, together with the cancer risks, demonstrate that the use of EDB in APHIS quarantine programs poses unusually high health hazards to the general public and to occupationally exposed workers.

The benefits resulting from this use of EDB, discussed in Chapter III, may amount to as much as 25 million dollars annually. This estimate is based largely on the assumption that if this registration were cancelled, the grapefruit export market to Japan would be eliminated, resulting in a loss to Florida growers of about 29 million dollars in revenue. However, this loss would be partially offset by an increase in the value of domestically produced mangoes and papayas, and also by the decrease in treatment costs.

It should be noted, however, that the estimated benefits from this use may be substantially overstated because they are based on the assumption that the grapefruit export market to Japan will be lost if this registered use is cancelled. The Agency recognizes that this export market was established on an understanding between the U.S. and Japan that grapefruits and certain other citrus destined for Japan from Florida will be treated with EDB prior to shipment as a quarantine measure against the spread of fruit flies. The loss of this export market rests on the assumption that if this registered use of EDB were cancelled, the Japanese would no longer accept Florida's citrus because it had not previously been treated with EDB. One possible option is to cancel the use of EDB on crops destined for consumption in the U.S., and allow its continued use on crops designated for export to Japan. However, it may happen that the Japanese government will decide that EDB fumigation is unacceptable and will not allow EDB-treated grapefruit and citrus to be imported. Thus, the actual impacts of cancelling this use of EDB depend on whether or not the Japanese will continue to require EDB treatments.

The underlying assumption that there are no viable alternatives to EDB for this use also has direct bearing on the estimated economic impact of cancelling EDB. There are no registered chemical alternatives for this use of EDB, nor are any approved non-chemical treatment methods presently available. Heat vaporization cooks the fruit, giving it an "off" taste; furthermore, there are no known available commercial vapor-heat chambers. Cold treatment damages grapefruit and other citrus; it cannot be used on mangoes or papaya, and causes a loss of about 10 percent in other miscellaneous fruits and vegetables.

However, gamma irradiation, a non-chemical method, is a promising substitute for EDB post-harvest fumigation. In many countries, irradiating foods with gamma radiation has been shown to be an economical, effective and safe method for eliminating pests from fresh foods. A number of foreign countries, including Japan, have approved and are using gamma radiation for food preservation and/or insect disinfestation. Appendix 2 lists the status by country of the acceptability of food irradiation. In the U.S., irradiation is subject to approval of the Food and Drug Administration (FDA) under the authority of the Food, Drug and Cosmetic Act. In fact FDA has already approved its use on for use on white potatoes and wheat (21 CFR 179.21). The Agency has had numerous meetings with both FDA staff and food irradiation experts to determine if irradiation of citrus should be considered as a potential substitute for this use of EDB. As a result, the Agency has concluded that irradiation is a potential substitute and should be a factor in developing a regulatory decision. This conclusion is based both on the Agency's recent discussions (Williams, 1980a and b; Savinski 1980; Welt, 1980a and b; Beeder, 1980a) and on recommendations made by the Interdepartmental Committee on Radiation Preservation of Food (ICRPF) in their report entitled, "Food Irradiation in the United States" (December, 1978).

Thus, the impact of cancellation of this use of EDB also depends on FDA approval of the use of gamma radiation as an insect disinfestation method for citrus and tropical fruits, as well as on Japan's acceptance of this substitute method. If the FDA approves and the Japanese accept irradiation of citrus as an alternative to EDB, then the current estimates of the benefits for this use of EDB may be significantly reduced. However, the Agency has not thoroughly studied the economic impacts of the use of irradiation.

2. Risk/Benefit Analysis

The Agency has evaluated the risks to human health and the economic benefits which result from current use practices and has concluded that this use causes unreasonable adverse effects to humans. Regulatory options available to the Agency to reduce these risks are listed in Table 30. This table shows the expected changes in risks and benefits which result from the implementation of each regulatory option.

Option 1, continued registration, would result in the indefinite continuation of unreasonable adverse effects both to the general population from dietary exposure and to workers applying EDB or handling treated fruit. The benefits of this use of EDB, approximately 25 million dollars annually, would remain unchanged.

Under Option 2, the Agency would impose restrictions to reduce risks for truckers, employees at fumigation centers and warehouse workers. Various means of reducing dietary exposure to the general population were explored in Chapter IV, however, none were considered to be effective or practical. Consequently, this option would only reduce risks to persons occupationally exposed to EDB. Risks to the general public would continue indefinitely because this option would have no impact on residues in citrus and tropical fruits. The benefits resulting from implementation of this option would remain essentially the same as in Option 1, because costs to impose the restrictions are small, about 13,000 per facility. (See Table 30).

Option 3 would permit EDB use to continue until a specific date. During the period of continued use, the restrictions specified in Option 2 would be imposed. Because there are currently no effective registered alternatives to EDB, selection of this option would allow for the development and implementation of alternative safer methods for use on quarantined commodities.

With implementation of this option the risks and benefits would change as the restrictions imposed change. The immediate impacts on risks and benefits, which would last until cancellation became effective, would be the same as those under Option 2 (i.e., reduced risks to applicators, continued high dietary risks to the general public, and essentially unchanged high economic benefits). Once cancellation became effective all EDB health risks would be eliminated, both to exposed applicators and to the general public from dietary exposure to EDB residues in treated commodities. The economic impact of cancellation, if gamma irradiation or another alternative became available, would be the capital investment costs, amortized over an appropriate period of time, plus the operating costs, minus the costs of treatment with EDB. The Agency has not examined these costs in detail, but has obtained some preliminary estimates of the operating costs for an irradiation facility with the capacity for effectively eliminating fruit flies on about 4 million pounds of packaged citrus per day (Welt, 1980a). At a minimum dosage level of 25 Krad, not to exceed 50 Krad, the estimated cost of processing is between $52 and $90 per 40,000 lbs of citrus. This cost estimate is based on 100,000 cases of grapefruit containing 40 lbs per case. Costs of the implementation and use of gamma radiation as a pesticide have been studied in great detail in a report entitled "Food Irradiation in the United States", prepared by the Interdepartmental Committee on Radiation Preservation of Food (December, 1980). Conclusions from this report were that "Use of chemical pesticides such as ethylene oxide, methyl bromide and ethylene dibromide could be reduced or eliminated."

Option 4 is immediate cancellation of the use of EDB to treat commodities destined for consumption in the U.S., while permitting its use to continue for fumigation of commodities destined for export, and requiring the same restrictions as would be imposed by Option 2 to reduce applicator risks. This option has three possible outcomes. The impact on risks and benefits depends on the possible outcomes. Under this option, dietary risks to the U.S. public would be eliminated and the risks to fumigation center and warehouse employees would be reduced. The economic impacts of this option could be highly variable depending on which outcome results. One outcome is that the Japanese government could continue to accept imported citrus which as been treated. If this outcome were to occur, the reductions in benefits could be small under the first outcome, amounting to an estimated $1.6 million. A second outcome of Option 4 is that the Japanese might decide to refuse EDB-treated citrus, in which case the economic loss to growers and the U.S. balance of trade would be large ($25 million and $27 million, respectively). A third possible outcome is that the U.S. could substitute gamma irradiation for EDB and still retain the Japanese export market. In this case, the economic impact on growers would be a change in treatment costs which the Agency has not evaluated.

Option 5 is immediate cancellation of all EDB used for post-harvest fumigation. This option would have significant impacts on both the risks and benefits of EDB. All risks of EDB would be immediately eliminated. Because the export market to Japan would be lost, the Agency estimates that citrus growers would lose $25 million in revenue losses and that there would be a net $18.4 million loss in the U.S. balance of trade.

Upon evaluation of the impacts each regulatory option has on the risks and benefits, the Agency has concluded that Options 1, 2 and 4 should be eliminated from further consideration and that only Options 3 and 5 should be examined in more detail. The reasons for eliminating the three options are as follows:

Option 1--continued unrestricted use--would result in the continuation of unreasonable adverse health effects to the general public, to the occupationally exposed worker including fumigation center employees, warehouse workers, and truckers, and to those individuals living around fumigation centers.

Option 2--classifying for restricted use and requiring fumigation center and warehouse modifications--would reduce the risks to workers through the implementation of these measures. The benefits would remain essentially unchanged. However, risks of unreasonable adverse effects to the U.S. population through dietary exposures to EDB would continue.

Option 4--immediately cancelling the use of EDB to fumigate commodities destined for consumption by the U.S. public, while retaining its use to fumigate commodities intended for export to foreign markets and imposing measures to reduce U.S. worker risks--would eliminate all dietary risks to the U.S. public and would reduce U.S. workers' risks. However, this regulatory option would announce to the international community that the Agency has not attempted to reduce the potential dietary residues and health risks which may be faced by countries importing U.S. treated commodities. The Agency views this option as a poor approach to the solution of an international environmental problem. The Agency rejects this option as an acceptable alternative.

The Agency has conducted an intensive comparative evaluation of the risks and benefits resulting from the implementation of Options 3 and 5.

Option 3--cancellation on a specific date of all uses of EDB to fumigate quarantined commodities, and in the interim requiring measures to reduce worker exposure--would allow the benefits of this use to continue until the date when cancellation becomes effective. The EDB health risks to workers would be reduced in the interim, while the benefits of approximately $25 million annually in revenue would be reduced only slightly by the costs to install worker exposure reduction measures. In addition, positive balance of trade payments of about $18 million annually would be retained. With no effective approved chemical or nonchemical alternatives to EDB currently available for this use, the interim period would allow for the replacement of EDB with a safer alternative.

However, until cancellation becomes effective, residues of EDB would continue to occur in fumigated food commodities, and the U.S. public would be at risk to unreasonable adverse effects resulting from dietary exposures to these commodities. Persons in countries that import commodities treated in the U.S. would be also potentially at risk to adverse health effects. The Agency has determined that the lifetime probability (70 yr) of EDB-induced cancer to

Table 30. Impacts of Regulatory Options on Post-Harvest Fumigation of Citrus, Tropical Fruits, and Vegetables

	EDB Human Health Risks		Risks of Substitutes	Economic Impacts		
Regulatory Option	Exposure Route	Risks	Human/Environmental	Users	Consumers	Comments
1. Continued Registration	Inhalation Dietary	See Tables 18 & 20 for cancer risks. See discussion in Chapter 5 for other possible risks.	Not Applicable	None	None	Unreasonable dietary and inhalation risks continue.
2. Classify for Restricted Use and require fumigation center and warehouse modification (see Chapter 4 for list of restrictions)	Same as Option 1	Reduced fumigation center and warehouse employee inhalation risks; dietary risks unchanged.	Not Applicable	$500.00 per each fumigation chamber $13,000 per fumigation center for monitoring and analytical devices. 1/	Minimal	Unreasonable dietary risks continue.
3. Option #2, plus cancel after a specific time period.	Same as Option 1	Same risks as for Option #2 except that all risks are eliminated after selected date when cancellation would become effective	Not Applicable	Option #2 plus unknown but probably moderate costs for installation of gamma irradiators or other alternative treatment methods which become available	Minimal	This option could allow time for alternatives to be developed and registered.

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[1] Per chamber cost includes expenses for installation of a closed EDB delivery system, ventilation equipment and safety devices (based on personal communication, J. Whitesides to J. Panetta 7/16/80).

Table 30. Impacts of Regulatory Options for Post-Harvest
(Cont.) Fumigation of Citrus, Tropical Fruits, and Vegetables

Regulatory Option	EDB Human Health Risks		Risks of Substitutes	Economic Impacts		Comments
	Exposure Route	Risks	Human/Environmental	Users	Consumers	
4. Immediately cancel use of EDB on crops consumed in the U.S., but allow continued use on exported commodities, with Option # 2 restrictions imposed.						
Possible Outcomes:						
A. Export market to Japan is retained because EDB-treated citrus is acceptable to Japan.	Inhalation	Reduced occupational risk; U.S. public dietary risks eliminated. Risks to Japanese unknown.	Not applicable	$1.6M (cost of using gamma irradiation not included).	Minimal	Assumes Japan will continue to accept EDB treated fruit.
B. Export market to Japan is lost because EDB-treated fruit is unacceptable to Japan.	None	All EDB risks eliminated.	Not applicable	$25M to users. $18M loss in balance of trade.	Consumer prices would be lowered due to excess supply of citrus in the U.S.	Assume citrus previously exported will be absored by U.S. market through price reductions.
C. Export market is retained through the substitution of irradiation. or other alternative treatment method	None	All EDB risks eliminated.	The occupational risks associated with use of irradiation in the U.S. are unknown, but likely to be negligible.	Cost of implementing and using irradiation.	None	Japan is already using irradation for use on some foods; however, radiation could not be adopted immediately in the U.S.

Table 30. Impacts of Regulatory Options for Post-Harvest
(Cont.) Fumigation of Citrus, Tropical Fruits, and Vegetables

Regulatory Option	EDB Human Health Risks Exposure Route	 Risks	Risks of Substitutes Human/Environmental	Economic Impacts Users	 Consumers	Comments
5. Immediately cancel use on both domestic and export crops.						
Possible outcomes:						
A. Export market to Japan is retained because irradiation or other alternative treatment is acceptable to Japan	None	All EDB risks eliminated	Occupational risks of using irradiation in the U.S. are unknown, but likely to be negligible	Same as 4C.	Minimal	Japan and other countries are already using irradiation as a food preservation technique. But irradiation could not be implemented immediately. No protection would be offered against the fruit fly until implementation of irradation.
B. Export market to Japan is lost because irradiation is unacceptable to Japan	None	All EDB risks eliminated	Not Applicable	$25M	Consumer prices would be lowered due to excess supply of citrus in the U.S.	Irradiation will likely not be used. Outcome results same as Option 4, Outcome B.

the average U.S. citizen is in the range of 10^{-4} for citrus and 10^{-5} for tropical fruit. Thus, for example, if the Agency chose 70 years as a date when cancellation of this use would become effective, one person in every 10,000 might incur cancer as a result of EDB residues in citrus, and one in every 100,000 from residues in tropical fruits. In addition to these risks,the public would also be at risk to reproductive disorders and mutagenic effects.

The Agency considers these high levels of risk resulting from lifetime exposure to be unacceptable, even in comparison with the considerable benefits of EDB for this use. To allow the use of EDB to continue for seventy years isunacceptable.

Option 5--would eliminate the risks of EDB entirely, and for this reason it has received serious consideration. Without appropriate alternative treatment methods however, this option would totally eliminate the benefits of EDB for quarantine use.

There is one vital consideration which the Agency has extensively investigated: whether gamma irradiation presents a viable alternative to EDB in the near future. As indicated previously, this method is effective and approved for use in many countries, but has not yet been approved for use in the U.S. The USDA APHIS has been researching this method for a decade, and since 1974 has been attempting to receive approval of its petition to FDA for use of gamma irradiation on mangoes and papays. USDA testing has also shown good results for citrus.

Recently, the EPA has met with the USDA and FDA to determine if USDA's petition for the use of irradiation as an alternative to EDB can be resolved. Based on these discussions FDA has accelerated its review and it appears that FDA could approve the use of gamma irradiation within 18 to 24 months. Based on the Agency's contacts with manufacturers who market irradiation systems, it appears that about 8 months would be required to install such systems (Welt, 1980a).

Based on this factor alone--that irradiation technology can be implemented within about 24 to 36 months--the Agency believes that Option 3 presents the best solution. With this option the dietary risks to the U.S. population would continue for 2 to 2 1/2 years. The estimated cancer risks are based on a 70 year lifetime exposure, the cancer risks associated with this interim period of 2 years would be about 2/70 of that risk, or about 10^{-6} for citrus and 10^{-7} for tropical fruit. In light of the large benefits of EDB that would continue for this period, the Agency finds that these lower risk levels would be acceptable, but only for the 2 to 2 1/2 yr period. Any further continuation of risk would be considered unreasonable. Regarding risks to applicators and warehouse workers, the Agency finds that implementation of the safety measures previously described would significantly reduce the risks to these persons without significantly effecting the economic benefits.

In conclusion, the Agency selects Option 3--phase-out of EDB after no more than 2 1/2 years from now, and immediate implementation of applicator and worker protection measures specified in Chapter IV or other measures to ensure that the EDB air standard of 0.4 ppm is met. A reasonable date for the cancellation to become effective would be July 1, 1983. After that date, no use of EDB will be allowed for post harvest commodity fumigation.

D. SPOT FUMIGATION OF GRAIN MILLING MACHINERY

1. Summary of Risks and Benefits

In Chapters II and III, the Agency evaluated the risks and benefits resulting from spot fumigation of milling machinery and cereal handling equipment. This periodic treatment with EDB of critical spots in grain milling machinery, ducts and conveyors is specifically timed to break the life cycle of invading pests, thus preventing the tremendous increase in pests which could result from the development of a second generation. The Agency has determined that this use of EDB, amounting to 465,000 pounds per year, causes health risks to the general public, mill workers, and fumigators. An investigation of alternatives revealed that the only effective alternative for this use of EDB is general space fumigation of the entire mill.

Recent studies which investigated the potential for residues of EDB to contaminate wheat flour following spot treatment confirm that flour does absorb residues and that they may persist for two weeks following treatment. The amount of EBD which contaminates flour varies greatly and depends on numerous factors including the length of time between spot treatment and wheat processing, the concentration of EDB in incoming wheat, and the construction of the flour mill. The Agency has determined that the average annual dietary burden resulting from this use of EDB ranges from 0.7×10^{-3} to 2.77×10^{-3} mg/kg/yr. The Agency's Carcinogen Assessment Group used these residue levels and estimated that the lifetime cancer risks to the U.S. public range from approximately 10^{-4} to 10^{-5}.

These residue levels and the corresponding dietary cancer risks are viewed by the Agency as upper bound estimates of the actual cancer risks. The estimated residue levels in bread include the assumption that all flour mills use EDB as the method of treatment of milling equipment for pest prevention. The number of mills using this process is unknown, as is the amount of wheat flour processed annually through these mills. In the absence of this information, the Agency has assumed that all mills use EDB.

The Agency has determined that spot treatment fumigators and mill employees are exposed to EDB vapors. These conclusions are based on findings from actual EDB air concentrations measured during and after spot treatment. To estimate the risks to fumigators of EDB-induced cancers, the Agency has considered both typical exposures and potential "worst-case exposures" (involving a fumigator who moved or adjusted his face mask). The estimated lifetime risks range from approximately 10^{-3} to 10^{-1} for applicators and 10^{-2} to 10^{-3} for mill workers.

EDB, used as a spot fumigant in flour mills, also presents potential risksof mutagenic effects and reproductive disorders to the general public, mill workers and fumigators. Although these risks have not been quantified, they must also be considered along with the cancer risks in weighing the risks and benefits of this general use of EDB.

The Agency estimates the economic benefits of spot fumigation to be in the range of 4.6 to 7.5 million dollars annually. These benefits are based on the assumption that, if this use of EDB were cancelled, the alternative would be general space fumigation with methyl bromide or aluminum phosphide. The costs are estimated to vary from 13 to 21 thousand dollars per year for individual wheat and rye mills, and from 8 to 14 thousand dollars per year for dry corn mills. The resulting annual consumer impacts would vary from an estimated 1.6 to 2.8 cents per capita per year for four general space fumigations, to 2.8 cents if five such fumigations are required.

The Agency has reviewed available data on the two substitute chemicals, methyl bromide and phosphine, the active ingredient and degradation product of aluminum phosphide. Unlike EDB, which is a liquid at room temperature (b.p. 131°C), the alternatives (methyl bromide and phosphine, the active ingredient of aluminum phosphide) are gases and would not be expected to leave significant residues on treated surfaces and commodities. Both phosphine and methyl bromide are acutely toxic, posing health hazards to unprotected applicators. However, available toxicology information and consideration of the physical properties of these chemicals lead the Agency to conclude that because of the low expected residue level, neither would cause unreasonable adverse chronic effects. Methyl bromide is known to cause mutations in some laboratory test systems. Application and ventilation practices which protect applicators from acute hazards should also provide significant protection to guard against the potential mutagenic hazards of methyl bromide.

2. Risk/Benefit Analysis

Based on the above risk and benefit information, the Agency has determined that the risks of adverse health effects exceed the economic benefits which result from the use of EDB in spot fumigation of grain mills. Therefore, unreasonable adverse effects to the public health exist and will continue to exist unless the Agency adopts regulatory options to reduce them.

This determination has led the Agency to evaluate several regulatory options which might reduce these risks. Table 31 presents the impact of each option on the risks and benefits of spot fumigation.

Option 1, continued registration, would result in continued risks of adverse health effects to the general population through dietary exposure, and to applicators and flour mill employees through dermal and inhalation exposures.

Option 2, imposing certain use restrictions see details in Chapter IV) would reduce applicator and general mill worker inhalation exposures to the NIOSH recommended level of 0.4 ppm. Applicator dermal exposures would also be reduced. However, this option would not reduce the residues of EDB which contaminate flour processed through grain milling equipment fumigated with EDB.

The intent of Option 3 is to achieve the same exposure reductions as Option 2, and also to lower the EDB-contamination of flour. By requiring that the first batch of flour, produced after a mill has been fumigated, be discarded, a portion of the EDB residues would be eliminated. However,the available information is not adequate to determine the degree of reductionin residues that might be achieved by this measure. Further, it would be difficult to enforce such a restriction or to expect a high degree of voluntarycompliance. Consequently, Option 3 would not likely result in a significantreduction of the dietary residues of EDB from spot fumigation.

The impacts of Option 4, cancelling use after 5 years and restricting use for the interim period, is the same as Option 3 until after the 5th year, at which time the impacts would be the same as Option 5, i.e., cancellation. The purpose of this option would be to allow time for flour mills to upgrade their facilities to use methyl bromide or aluminium phosphide.

Table 31 Impacts of Regulatory Options for Spot Fumigation

Regulatory Options	EDB Human Health Risks		Risk of Substitutes		Economic Impact		Comments
	Exposure Route	Risks	Human	Environmental	Users	Consumers	
1. Continued Registration	Dietary Inhalation and Dermal	See Tables 18 and 20 for cancer risks and discussion in Part II for other possible risks.	Not Applicable		None	None	
2. Classify for Restricted Use; impose use restrictions listed in Part IV	Same as Option 1	Dietary Risks continue. Reductions in applicator and non-applicator risks.	Not Applicable		Respirators and clothing cost about $100. Label and reentry impacts are negligible.	None	Applicators would probably comply with restrictions.
3. Option 2 human consumption of flour milled during the first several hours after EDB-treatment	Same as Option 1	Reduced applicator and non-applicator risks. Dietary risks should be reduced but the amount of reduction is not known.	Not Applicable		Cost of discarding flour was not analyzed, but is probably minor.	Negligible	Flour mills might not comply with the holding restriction and enforcement would be difficult.
4. Cancel after 5 years and impose Option 3 for the interim	Same as Option 1	Risks same as in Option 3 for 5 years; no risks after 5 years.	After 5 years, the risks of alternatives are the same as in Option 5.		None	None	During the 5 year period, some mills could modify their facilities for use of methyl bromide or aluminum phosphide
5. Cancel Immediately	No Exposures	All EDB risks eliminated	Aluminum phosphide (AP) and methyl bromide (MB) are acutely toxic MB is a suspect mutagen		$5.1-$6.4M per year for 298 wheat and rye mills; $1.3M/yr. for 93 corn mills. Total max. impact = $7.7 M/yr	1.6 to 2.8 cents per capita	

Immediate cancellation, Option 5, would force EDB users to switch immediately to alternative fumigants at a total increased treatment cost of $7,700,000 per year for all 391 grain mills, or 2.8 cents per consumer. While this is a "worst-case" estimate (because it assumes all mills now use EDB), the potential cost of upgrading some mills to allow maximum effectiveness from space fumigation has not been included. In any event, this option would eliminate the risks of EDB and would result in use of apparently safer substitute fumigants.

As the data presented in Table 31 demonstrate, any action short of immediate cancellation will result in continued dietary risks. If the Agency were to classify EDB for restricted use, or amend the terms and conditions of registration, some users may continue to apply EDB rather than switch to alternatives. Although occupational risks would be reduced, this option would not result in a reduction in the risks to the general public resulting from dietary exposure.

In conclusion, the Agency believes that the health risks of EDB are serious and unacceptable when considered with the benefits, and will only be reduced through immediate cancellation. Cancellation will not result in unreasonable economic costs to grain mills or consumers. There are alternative chemical fumigants for this use which the Agency believes will not cause the public and properly protected applicators to be at risk to the range or magnitude of serious adverse health effects that exist with use of EDB.

E. PRE-PLANT SOIL FUMIGATION

1. Summary of Risks and Benefits

The Agency has evaluated the human health risks and economic benefits of the use of EDB as a pre-plant soil fumigant. The health risks of concern are oncogenicity, mutagenicity and reproductive effects. These risks exist for fumigation applicators and other individuals directly involved in application operations, and might exist for the general public potentially exposed to EDB residues in crops grown in fumigated soil.

The maximum hypothetical risks to humans resulting from potential dietary exposure were estimated for the 16 soil-fumigated crops listed in Table 8 of Chapter II. As discussed in Chapter II, no detectable residues of EDB have been found at a level of detection of 0.001 ppm. Although the analytical method used in these tests has not been completely validated, the Agency assumes that residues will not exceed this level. To determine an upper-bound lifetime probability of EDB-induced cancer resulting from dietary exposure, the Agency conservatively assumed that EDB residues are present at this level of detection. Based on the assumption that a maximum of 0.001 ppm EDB is present in each soil-fumigated crop, the maximum lifetime probability of EDB-induced cancer for the general public varies from approximately 10^{-6} to 10^{-5}. However, because actual levels of EDB are probably below 0.001 ppm, the actual cancer risks are also expected be lower than these maximum risk estimates. The Agency has also concluded that if residues do occur, they also pose a potential risk of genetic damage and reproductive disorders to man.

Soil fumigation applicators and those individuals involved in the transfer of soil fumigants are likely to incur inhalation and dermal exposures during EDB soil application and transfer. Soil fumigation operators are exposed to EDB ranging from 0.7 mg/yr for peach crops to between 303.3 and 532.4 mg/yr for pineapples. The Agency used these exposures to estimate that the life time risk of EDB-induced cancer to soil fumigators is in the range of 10^{-5} to 10^{-3}. As discussed in Chapter II, the Agency has also concluded that exposures to EDB may result in hazard of genetic damage and reproductive problems to exposed individuals.

In addition to the potential for residues occurring in crops, the Agency is concerned that EDB might leach into groundwater as a result of current use practices. Although no data are available on the leaching potential of EDB, residues of the soil fumigant dibromochloropropane (DBCP), which has similar use sites and use practices and chemical properties, have been found in ground water. The Agency views this data gap as a significant issue which must be resolved before final regulatory measures can be determined for this use. As a result, the regulatory actions proposed for this use should be considered as interim measures which will be finalized when adequate information is available to evaluate this issue.

The Agency has evaluated the economic impact of cancelling soil fumigation with EDB and has determined that this use has substantial economic benefits. All alternative treatment methods would be more expensive to farmers. Depending on the crop treated, the total increased costs to farmers of using alternative fumigants would vary from $3,500 for citrus to $3,800,000 for vegetables. The total user impacts of cancelling all preplant soil fumigation uses would approach $21,000,000.

Numerous alternative pesticides are available for use as soil fumigants in place of EDB. The major alternatives in most cases are equally as efficacious as EDB. The alternatives for most crops are DD, Telone II and Vorlex. For pineapple uses, DBCP must be used in combination with DD or Telone. There are both substantial health risks as well as a number of data gaps associated with these substitutes, as shown in Table 26. A recent NCI study shows Telone to be oncogenic. DD and Telone have been demonstrated to be mutagenic in laboratory tests. DBCP is currently suspended for all uses except on pineapples due to its oncogenic, mutagenic and reproductive hazards. The remaining alternatives (Vorlex, Vemacur, Mocup, and Dasanit) have data gaps for most chronic effects hazards.

2. Risk/Benefit Analysis

Based on the above risk and benefits information, the Agency has concluded that there are significant health risks to soil fumigation applicators due to exposure to EDB. The risks of cancer, mutagenic effects and reproductive disorders to the occupationally exposed exceed the economic benefits for EDB soil fumigation. Therefore, it is necessary that the Agency consider appropriate regulatory options to reduce these potential "unreasonable adverse effects to the public health." The Agency considers the potential for EDB residues to occur in water supplies and crops grown in fumigated soils to be data gaps which must be resolved. The regulatory measures which are developed below are interim actions intended to reduce the health risks of EDB use as a soil fumigant. When the data gaps are resolved, the Agency will reevaluate this use to determine if additional regulatory measures are needed.

Table 32 identifies three possible regulatory options. They are in order of increasing restriction: continued registration without restrictions, continued registration with restrictions, and cancellation. Changes in the risks and benefits of EDB expected to result from each option are also shown.

Table 32 Impacts of Regulatory Options on Soil Fumigation

Regulatory Options	EDB Human Health Risks		Risk of Substitutes	Economic Impacts		Comments
	Exposure Route	Risks	Human/Environmental	Users	Consumers	
1. Continued Registration	Inhalation and Dermal for applicators. Potential dietary and drinking water for the general public.	See Table 18 and 20 for cancer risks and discussion in Chapter 5 for other possible risks.	Not applicable	None	None	Unreasonable applicator health risks continue. Data gaps exist for groundwater contamination and food residues.
2. Continue Registration, but require Applicator Use Restrictions, Set Tolerances for EDB in Food Crops, Require Studies of Leaching Potential and Food Residues	Inhalation and Dermal for applicators. Potential dietary and drinking water. for the general public.	Dermal and inhalation exposure risks reduced	Not applicable	$175.00 to $600.00 per applicator	None	Monitoring and enforcement will be necessary. Monitoring data needed for potential of groundwater and food contamination. EDB tolerances must be established.
3. Immediate Cancellation	All EDB risks eliminated		DD and Telone are oncogenic and suspected mutagens. Vorlex is acutely toxic, but has no chronic effects data.	$3,500 to $3.8M, depending on use-site.	None	All substitutes present potential risks to human health.

Option 1, continued registration without restrictions, would result in unreasonable adverse effects to applicators, as concluded above. Until more definitive data are provided by registrants, the Agency also assumes that risks to the public may result from potential exposure to EDB in food and/or drinking water.

Option 2, continued registration with restrictions, would significantly reduce risks to applicators, but would have no impact on the risk from potential residues in food or drinking water. As a component of this option, the Agency will require a study of the potential of EDB to contaminate food crops grown in EDB-fumigated soils, and laboratory and field studies of the leaching potential of EDB. The food residue study will investigate if residues of EDB in crops grown in EDB-fumigated soils (at maximum application rates) do not exceed the current limit of sensitivity of analytical methodology of .001 ppm. The studies on the leaching potential of EDB will be subject to the Agency's review and evaluation prior to commencement.

Immediate cancellation, Option 3, would result in significant economic costs to growers, but would eliminate all health risks from EDB. Losses to growers would amount to almost 21 million dollars. In addition, if this use were cancelled, users would substitute other soil fumigants which may also pose significant health hazards and have numerous data gaps. If this use were immediately cancelled, the Agency would have no assurance that the net risks to public health would decrease.

The Agency selects Option 2 as the appropriate regulatory option for three reasons: First, this option will establish risk reduction measures which lower applicators' risks at a reasonable cost. The specific use restrictions for the protection of soil fumigation applicators include all those measures specified in Chapter IV: classifying EDB for restricted use by certified applicators only; requiring applicators to wear a NIOSH/MSHA-approved full face black canister respirator during application; establishing a 24-hr post-application period during which any person reentering the treated area must wear a respirator; requiring EDB-resistant (butyl rubber) gloves and boot covers (butyle rubber, nitrile or polyethylene) be worn during mixing and loading of EDB as well as during the maintenance of application equipment; and requiring signs be posted on the treated site to notify readers of the treatment with EDB and bearing further warning information. These restrictions will result in a significant reduction in worker exposure, while maintaining the economic benefits of EDB.

The second reason for selecting Option 2 is that the risks to public health (pending resolution of the data gaps) which might result from the undetected but possible exposure to EDB, are outweighed by the economic benefits. In determining the risk of cancer due to consumption of EDB-fumigated crops, the Agency assumed that a maximum of 0.001 ppm of EDB was present on each crop. The estimate derived from this assumption is presumed to be a worst-case estimate because EDB has not been detected in analytical tests on such crops at a level of detection of 0.001 ppm. To ensure that any EDB residues remain acceptably low (i.e., < .001 ppm), the Agency proposes to establish a tolerance for residues at the level of detection of EDB per se in or on food crops grown in EDB fumigated soils.

The third reason for choosing Option 2 is that it will enable the Agency to resolve the data gaps concerning the potential for EDB to contaminate food crops and/or to leach into water supplies. Until these data are available, it is not possible to estimate quantitatively the risks for these health hazards of EDB. The Agency therefore proposes to use Section 3(c)2(B) of FIFRA to quickly obtain these additional data. When results of these studies are available and have been evaluated, the Agency will reevaluate whether additional regulatory actions are needed for this use.

Following the suspension of DBCP as a preplant for soybean nematode control in 1979, several states have claimed there are no other registered pesticides that are economical or effective against nematodes. Based on the available test results showing EDB to be as efficacious as DBCP, six states applied for temporary permits (e.g., exemptions from FIFRA) to allow this use under section 18(c) of FIFRA. These exemptions were granted with the requirement that numerous restrictions be implemented to reduce exposures to EDB and the associated health risks to applicators. These exemptions were granted for the period beginning April 24, 1980 and ending July 31, 1980. Table 3 lists these restrictions, those applicants who applied for and received exemption, the area and acreage to be covered, target pests, and the EDB products approved for each use.

F. Minor Uses--Beehive Supers, Vault Fumigation, Termite Control, Bark Beetle Control, and Japanese Beetle Control

1. Summary of Risks and Benefits

The Agency has examined the potential human health risks and the economic benefits for four of the five known lower volume uses of EDB. A risk/benefit evaluation of the fifth use--subterranean and drywood termite control--will be deferred until a cluster analysis for all pesticides used for termite control is conducted. The uses which are evaluated in this section include fumigation of stored beehive supers and honeycombs (to control greater wax moth larvae), vault fumigation of stored clothing and furniture (to control various pests), treatment of felled logs (to control bark beetles), and treatment of APHIS quarantined plants, soil and grass sod (to control Japanese beetles). The health risks include cancer, genetic damage, and reproductive disorders.

As discussed in Chapter II, quantitative estimates of the risks are not available for most of these uses. However, as discussed below, an examination of the use practices for each of these uses reveals that applicators are likely to be exposed to EDB during use and that they may be at risk to unreasonable adverse effects.

Vault fumigation involves the pouring of EDB into a heating device, which evaporates the EDB to penetrate items being treated. The formulation used in vault fumigation is 5% EDB and the period for fumigation is generally 16 hours. Thus, vault fumigators can be exposed dermally during the pouring of the formulation into dispensing containers and through inhalation during pouring and when reentering the vaults. The Agency currently has no information on the amount of EDB used annually for vault fumigation, how many of these facilities exist in the U.S., how many vault fumigation employees there are in the U.S., or the levels of EDB to which vault fumigation can be exposed.

No data exist on the exposures of beekeepers to EDB. However, use practices for the fumigation of stored beehive supers suggest that beekeepers may be exposed both through inhalation and dermal contact but less frequently than applicators for all other registered uses of EDB. Because this fumigation procedure is an annual practice among certain beekeepers, exposures only occur once a year when stored hives and supers are treated during the off season.

Generally, one to two tablespoons of 83% EDB formulation are placed on absorbent material which is set on stacked supers; the stack is then covered with plastic sheeting for 24 hours. Both dermal contact and inhalation of vapor can occur during use. But the Agency has no estimate of the air levels of EDB that could result from such use practices, nor of the frequency or quantity of EDB dermal contact which could occur. However, the number of beekeepers who use EDB could be large, because 20,000 lbs. of EDB are estimated to be used annually for fumigation of supers and hives.

A separate but related issue for this use of EDB is the possibility that EDB residues could occur in honey as a result of application to stored honeycombs. As discussed in Chapter II, the Agency has no data on EDB in honey, but views this as a very unlikely possibility. The Agency considers it as a data gap which must be resolved to determine the total health risks which may exist for this use.

No information exists on the EDB air levels to which individuals are exposed during the treatment of felled logs. However, current use practices suggest that both dermal contact and inhalation exposures will likely occur during this use. Generally, a formulation of 23% EDB is applied to felled logs in one of two ways: spraying to the point where runoff of liquid occurs, or spraying at a lower rate to stacks of wood which are subsequently covered under a plastic sheet. Applicators thus may be exposed to EDB dermally and through inhalation of vapors during loading of sprayers as well as during actual use. The use of plastic sheeting appears to offer some protection against inhalation exposure both because it captures vapors and because of the reduced quantity of formulation needed. Though the Agency has estimated that 20,000 lbs. of EDB were used in 1977, enough to treat an estimated 68,000 trees, there is no information on the number of users or the frequency of use.

For fumigation of quarantined plants, soil and grass sod, the Agency has no information on applicator exposures, number of applicators, frequency of use by applicator, or the amount of EDB used for this site. This use is required by 7 CFR 301.48 (APHIS Japanese Beetle Domestic Quarantine Program). Current use practices suggest that users may be exposed both through dermal contact and to inhalation of EDB vapors. For each of these uses, EDB comprises either 2.5% or 20% of the formulation (see Benefits Chapter). For all applications, the formulation is mixed with water and applied in very low concentrations. During the mixing of the formulation with water, users may contact EDB dermally or via inhalation. During application of the diluted solution, exposure of users to EDB will also occur. Because this solution contains very small quantities of EDB, exposures are likely to be very low.

The four minor uses of EDB each have economic benefits. For beehive supers the benefits are considerable, amounting to more than $10 million annually. EDB is more effective than either of the alternatives, paradichlorobenzene (PDB) and carbon dioxide. PDB is generally much more practical to use than CO_2, which requires elaborate monitoring equipment to ensure efficacy. The substitution of PDB would result in increased treatment costs of about $3.7 million annually (approximately 5 cents per super) due to its higher cost and to the additional treatments required. Because the alternatives are not as effective as EDB, the quantity of domestic honey produced would be reduced by an estimated 6 percent annually, resulting in a loss to beekeepers of $6.5 million. A production loss of this magnitude would shift some of the cost impact to the consumer, but the extent of this impact cannot be estimated.

Use of EDB on infested, felled trees to control the pine bark beetle in western states, primarly benefits private land-owners. Although the extent of EDB use does not appreciably affect the value of commercial timber harvests, control of the pine bark beetle on residential lots may prevent tree mortality losses of $1,500 to $3,000 per lot. The use of the alternative endosulfan could actually reduce total costs by as much as $36,000 annually, in spite of the fact that it may not be as effective as EDB. The other alternative, lindane, could reduce treatment costs by up to $16,000 annually. However, because lindane is in RPAR and is recommended for cancellation for thus use, it was not evaluated as a viable alternative.

The extent of the use of EDB in both vault fumigation of stored clothing and furniture, and in the APHIS/USDA Japanese beetle quarantine program is unknown. The economic benefits therefore, could not be quantified. A registered acceptable alternative in the APHIS/USDA quarantine program is methyl bromide. Four registered alternatives are available for vault fumigation: a carbon tetrachloride/ethylene dichloride mixture, chloropicrin, methyl bromide, and sulfuryl fluoride. However, methyl bromide requires extreme care in use, as described in Chapter III.

2. Risk/Benefit Analysis

The Agency has concluded that sufficient information exists to propose cancelling the use of EDB to fumigate felled logs. The basis for this decision lies in the fact that applicators are at risk to unreasonable adverse effects of EDB, and because there are no known benefits for this use. Use of endosulfan in place of EDB would result in a total reduction in treatment costs of about $36,000 annually, even though it is not as effective as EDB. The Agency concludes that the potential health risks to applicators through both dermal contact and inhalation exposures to EDB outweigh these negative benefits.

In view of the lack of risk and benefit information for the remaining three uses, the Agency is unable to perform an adequate risk-benefit balancing analysis. However, because applicators could potentially experience unreasonable adverse effects of EDB, the Agency will require registrants to submit certain data necessary to adequately evaluate the risks and benefits of each of these lower uses. Because time will be needed to obtain these data, evaluate it, and perform a thorough risk-benefit balancing, for the interim the Agency has examined a number of actions designed to reduce applicator risks at a minor cost. Summarized below by use are actions the Agency is proposing and data which the Agency will require of registrants. These are organized on a use-by-use basis for three of the four minor uses: fumigation of beehives and supers, APHIS Japanese Beetle Control Program, and vault fumigation.

For fumigation of beehive supers and honeycombs, the Agency is proposing the following interim label changes for such EDB products:

Certified Applicators -- Fumigation may be conducted only by or under the supervision of a certified applicator.

Protective Clothing -- EDB-resistant gloves (butyl rubber only), boot covers and apron (made of butyl rubber, nitrile, or polyethylene) will be worn at all times.

Use Directions -- Supers and honeycombs must be placed in a gas-tight room or under a gas-tight covering such as a polyethylene tarpaulin held down with sand-filled "snakes." All windows, doors and vents must sealed. All persons not involved with the fumigation must be vacated from the building.

Reentry Period -- Following the treatment period, a full-face, black canister respirator must be worn when reentering. All doors, windows and vents must be opened at this time. Aeration for 24 hours or until EDB air levels are less than 0.4 ppm measured by IR detector shall be required before reentry is permitted. The label and warning signs (See Chapter IV) must contain this information.

Limit fumigation to beehive supers that are clean and in storage. -- To avoid possible contamination of honey or honeycombs, the label will prohibit treatments other than on clean supers or comb mounted in frames in storage. This restriction is in accordance with current practice.

In addition to these label changes, the Agency is proposing to require the following data from registrants:

1. EDB air levels to which applicators are exposed during typical conditions of use.

2. Number of users.

3. Residue studies to determine if EDB is detectable in honey from fumigated supers and combs.

For vault storage, the Agency is proposing to require the following label changes and use restrictions:

Protective Clothing -- Require the same protective clothing listed for beehive supers.

Certified Commercial Applicators -- Vault fumigation may be conducted only by certified commercial applicators in commercial fumigation vaults.

Use Directions -- Before fumigation, all doors and leaks in the vault must be sealed. All persons not involved with the fumigation must be vacated from the building.

Reentry Period -- Following the treatment period, a full-face, black canister respirator must be worn during reentry. All doors and vents in the treatment area and connected buildings must be opened at this time. Premises must be aerated 24 hours or until EDB levels are less than 0.4 ppm as measured by IR detector before reentry is allowed. Posted warning signs (See Chapter IV) must bear this information.

In addition to these label changes, the Agency proposes to require the following information from registrants:

1. Monitoring studies of the EDB air levels to which applicators may be exposed, both during pouring EDB into dispensing containers and also during reentry into the vault after fumigation.

2. Survey data on the number of vault fumigation operations using EDB and the number of applicators involved in this practice; and

3. Data on the amount of EDB applied annually for this use.

For the APHIS Japanese Beetle Control Program, the Agency is proposing to require the following label restrictions and revisions in the APHIS Manual:

Grass sod -- Treated sod must be covered with a heavy plastic or tarp during the treatment period to ensure an efficacious treatment and to minimize air exposures. The tarp must be aired before re-use.

Bareroot Plants -- The proper method for disposing of the used EDB-water mixture must be specified.

Balled or Containerized Plants -- The "enclosed place" into which plants are placed after treatment must be posted with signs indicating the minimal reentry information described previously. Proper disposal methods must be described.

Potting and Bench Soil -- Soil must be covered with plastic or heavy tarp for duration of the treatment period.

Beds and Other Uses -- Soil must be covered with plastic or heavy tarp for duration of the treatment period.

For All Above Uses -- The APHIS Manual states for balled or containerized plants that treatment is approved only when beetle grubs (larvae and pupae) are present. This requirement must be imposed for all regulated articles to avoid unnecessary applications.

For this use, the Agency is proposing to require the following information:

1. Monitoring studies of the air levels to which applicators are exposed during mixing and during use.

2. Data on the amount of EDB used annually, the number of applicators and the frequency of use.

In addition to these actions, the Agency is proposing to require certain interim measures for the use of EDB in the control of termites. As discussed earlier, the Agency is proposing to defer a risk/benefit balancing decision for this use and will include it in a cluster analysis of all pesticides used for termite control. In the interim, however, the Agency recognizes that both applicators and persons in the immediate treatment area can be exposed and are therefore at risk to unreasonable adverse affects. To reduce exposures of applicators and non-involved persons to EDB, the Agency proposes the following use restrictions be included on the label:

Certified Commerical Applicators -- Fumigation may be conducted only by a certified commercial applicator wearing a full-face, black canister respirator;

Protective Clothing -- EDB-resistant gloves, boot covers and apron will be required at all times;

Use Directions for Drywood Termites -- Persons not involved with the fumigation must leave the premises. Holes of size and spacing specified by the registrant must be drilled and the recommended dosage of EDB injected into these holes using a calibrated syringe or like device.

Use Directions for Subterranean Termites -- Persons not involved with the fumigation must leave the premises before fumigation and subsequent aeration. Use is not permitted under slabs which contain air ducts, electrical conduits, or the like. Recommended dosage must be injected through holes drilled in concrete slabs which support infested structures. All holes must be plugged temporarily to prevent the escape of EDB during treatment, and must be sealed permanently immediately after treatment. The label must state these requirements.

Reentry Period -- During and after fumigation all doors, windows and vents in the treatment area and connected buildings would be opened. Premises must be aerated 24 hours or until EDB air levels are below 0.4 ppm before reentry is permitted. The label and posted warning signs must contain this information.

In addition, the Agency is proposing to require registrants to provide data which would be needed in the cluster analysis. These data are:

1. Air concentration of EDB to which applicators are exposed, their annual time spent using EDB, the number of applicators using EDB in the U.S., and the amount of formulation sold annually; and

2. Air monitoring studies which investigate the potential EDB air levels to which persons not involved can be exposed. These would include indoor places at or near the site(s) of application.

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APPENDIX 1

RESPONSES RECEIVED REBUTTING HEALTH TRIGGERS

Rebuttal No.	Source	Date of Submission 1/
3C	Great Lakes Chemical Corporation	01/23/78
7	Chevron Chemical Company	01/16/78
13	University of Idaho Cooperative Extension Service	01/19/78
14	Department of Citrus, State of Florida	01/20/78
15	Millers National Federation	01/24/78
15A	Millers National Federation	04/07/78
15B	American Corn Millers Federation	04/07/78
16	Colorado State University	01/26/78
22	Ferguson Fumigant Inc.	01/31/78
22A	Ferguson Fumigant Inc.	02/01/78
22B	Ferguson Fumigant Inc.	04/04/78
22C	Ferguson Fumigant Inc.	04/13/78
22D	Ferguson Fumigant Inc.	06/01/78
26	Pineapple Growers Association of Hawaii, Honolulu	12/12/77 2/
31	Florida Agricultural Research Institute	01/31/78
32	Florida Farm Bureau	01/31/78
33	Department of Agriculture Honolulu, Hawaii	01/31/78
47	Douglas Chemical Company	02/09/78
47A	Douglas Chemical Company	04/13/78
48	Ethyl Corporation	01/31/78
64	Vulcan Materials Company, Chemical Division	04/03/78
65	Florida Citrus Commission	04/03/78

66	Environmental Defense Fund	04/04/78-04/03/78
78	Dow Chemical	04/26/78
79	Cooperative Extension, University of California	04/11/78

1/ Dates given are the dates OPP's Federal Register Section received the submission.

2/ Three additional addenda were submitted on this rebuttal.

APPENDIX 2

FROM FOOD IRRADIATION NEWSLETTER
OCTOBER 79, IAEA

LIST OF CLEARANCES

GENERAL SURVEY OF IRRADIATED FOOD PRODUCTS CLEATED FOR HUMAN CONSUMPTION IN DIFFERENT COUNTRIES

(Grouped according to country)

August 1979

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION	DOSE (k Gy)	DATE OF APPROVAL
BULGARIA	potatoes *)	sprout inhibition	+		1971
	potatoes *)	sprout inhibition	+	0.1	30 April 1972
	onions *)	sprout inhibition	+	0.1	30 April 1972
	garlic *)	sprout inhibition	+	0.1	30 April 1972
	grain *)	sprout inhibition	+	0.3	30 April 1972
	dry food concentrates *)	insect disinfestation	+	1	30 April 1972
	dried fruits *)	insect disinfestation	+	1	30 April 1972
	fresh fruits *) (tomatoes, peaches, apricot, cherry, raspberry, grapes)	radurization	+	2.5	30 April 1972

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION			DOSE (k Gy)	DATE OF APPROVAL
			^{60}Co	^{137}Cs	elec- trons		
CANADA	potatoes	sprout inhibition	+			0.1 max	9 November 1960
						0.15 max	14 June 1963
	onions	sprout inhibition	+			0.15 max	25 March 1965
	wheat, flour, whole wheat flour	insect disinfestation	+			0.75 max	25 February 1969
	poultry ****)	radicidation (Salmonella)	+			7 max	20 June 1973
	cod & haddock fillets ****)	radurization	+			1.5 max	2 October 1973
CHILE	potatoes *) ****)	sprout inhibition	+				31 October 1974
CZECHOSLOVAKIA	potatoes *)	sprout inhibition	+			0.1 max	26 November 1976
	onions *)	sprout inhibition	+			0.08 max	26 November 1976
	mushrooms *)	growth inhibition	+			2 max	26 November 1976
DENMARK	potatoes	sprout inhibition			10 MeV	0.15 max	27 February 1970

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION ^{60}Co	^{137}Cs	electrons	DOSE (k Gy)	DATE OF APPROVAL
FRANCE	potatoes **)	sprout inhibition	+			0.075 - 0.15	8 November 1972
	onions **)	sprout inhibition	+	+		0.075 - 0.15	9 August 1977
	garlic **)	sprout inhibition	+	+		0.075 - 0.15	9 August 1977
	shallot **)	sprout inhibition	+	+		0.075 - 0.15	9 August 1977
FRG	deep-frozen meals *) ***)	radappertization	+			25 -45	24 March 1972
	potatoes *)	sprout inhibition	+			0.15 max	26 September 1974
HUNGARY	potatoes ****)	sprout inhibition	+			0.1	23 December 1969
	potatoes ****)	sprout inhibition	+			0.15 max	10 January 1972
	potatoes ****)	sprout inhibition	+			0.15 max	5 March 1973
	onions ****)	sprout inhibition	+				5 March 1973
	onions ****)	sprout inhibition	+			0.06	6 August 1975
	onions *)	sprout inhibition	+			0.06	6 September 1976
	strawberries ****)	radurization	+				5 March 1973

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION ^{60}Co	^{137}Cs	electrons	DOSE (k Gy)	DATE OF APPROVAL	
HUNGARY (cont'd.)	mixed spices *) (blackpepper, cumin, paprika, dried garlic: for use in sausages)	radicidation	+			5	2 April	1974
	mixed dry ingredients for canned hashed meat *) (wheat flour, Na caseinate, onions and garlic powder, paprika)	radiation decontamination	+			5	20 November	1976
ISRAEL	potatoes	sprout inhibition	+			0.15 max	5 July	1967
	onions	sprout inhibition	+			0.1 max	25 July	1968
ITALY	potatoes	sprout inhibition	+			0.075 - 0.15 max	30 August	1973
	onions	sprout inhibition	+			0.075 - 0.15	30 August	1973
	garlic	sprout inhibition	+			0.075 - 0.15	30 August	1973
JAPAN	potatoes	sprout inhibition	+			0.15 max	30 August	1972

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION			DOSE (k Gy)	DATE OF APPROVAL
			^{60}Co	^{137}Cs	electrons		
NETHERLANDS	asparagus *)	radurization	+			2 max	7 May 1969
	cocoabeans *)	insect disinfestation	+		4 MeV	0.7 max	7 May 1969
	strawberries ****)	radurization	+		4 MeV	2.5 max	7 May 1969
	mushrooms	growth inhibition	+		4 MeV	2.5 max	23 October 1969
	deep-frozen meals ***)	radappertization	+			25 min	27 November 1969
	potatoes	sprout inhibition	+		4 MeV	0.15 max	23 March 1970
	peeled potatoes ****)	radurization	+			0.5	12 May 1976
	shrimps *)	radurization	+		4 MeV	0.5 - 1	13 November 1970
	shrimps ****)	radurization	+			1	15 June 1976
	onions *)	sprout inhibition	+			0.15 max	5 February 1971
	onions	sprout inhibition	+			0.05 max	9 June 1975
	poultry, eviscerated (in plastic bags)	radurization	+			3 max	31 December 1971

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION			DOSE (k Gy)	DATE OF APPROVAL
			^{60}Co	^{137}Cs	electrons		
NETHERLANDS (cont'd.)	chicken	radurization, radicidation	+			3 max	10 May 1976
	fresh, tinned & liquid foostuffs ***)	radappertization	+			25 min	8 March 1972
	spices & condiments *)	radicidation	+		4 MeV	8 - 10	13 September 1971
	spices **)	radicidation	+		4 MeV	10	4 October 1974
	spices **)	radicidation	+		3 MeV	10	26 June 1975
	spices **)	radicidation	+			10	4 April 1978
	vegetable filling *) ****)	radicidation	+			0.75	4 October 1974
	powdered battermix ****)	radicidation	+			1.5	4 October 1974
	endive ****) (prepared, cut)	radurization	+			1	14 January 1975
	fresh vegetables ****) (prepared, cut, soupgreens)	radurization	+			1	6 September 1977

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION			DOSE (k Gy)	DATE OF APPROVAL
			^{60}Co	^{137}Cs	elec-trons		
NETHERLANDS (cont'd.)	fillets of haddock, coal-fish, whiting ****)	radurization	+			1	6 September 1976
	fillets of cod & plaice ****)	radurization	+			1	7 September 1976
	frozen frog legs **)	radicidation	+			5	25 September 1978
	rice and ground rice products **)	disinfestation	+			1	13 March 1979
PHILIPPINES	potatoes **)	sprout inhibition	+			0.15 max	13 September 1972
SOUTH AFRICA	potatoes	sprout inhibition delayed greening	+			0.12 - 0.24	19 January 1977
	onions	sprout inhibition	+			0.05 - 0.15	25 August 1978
	garlic	sprout inhibition	+			0.1 - 0.20	25 August 1978
	chicken	radurization radicidation	+			2 - 7	25 August 1978
	papaya	radurization	+			0.5 - 1.5	25 August 1978

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION ^{60}Co	^{137}Cs	elec-trons	DOSE (k Gy)	DATE OF APPROVAL
SOUTH AFRICA (cont'd.)	mango	radurization	+			0.5 - 1.5	25 August 1978
	strawberries	radurization	+			1 - 4	25 August 1978
	dried bananas +)	insect disinfestation	+			0.5 max	28 July 1977
	avocados +)	delayed ripening	+			0.1 max	28 July 1977
SPAIN	potatoes	sprout inhibition	+			0.05 - 0.15	4 November 1969
	onions	sprout inhibition	+			0.08 max	1971
THAILAND	onions	sprout inhibition	+			0.1 max	20 March 1973
UNION OF SOVIET SOCIALIST REPUBLICS	potatoes	sprout inhibition	+			0.1	14 March 1958
	potatoes	sprout inhibition			1 MeV	0.3	17 July 1973
	grain	insect disinfestation	+			0.3	1959
	fresh fruits & vegetables *)	radurization	+			2 - 4	11 July 1964

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION			DOSE (k Gy)	DATE OF APPROVAL
			^{60}Co	^{137}Cs	elec-trons		
UNION OF SOVIET SOCIALIST REPUBLICS (cont'd.)	semi-prepared raw beef, pork & rabbit products (in plastic bags) *)	radurization	+			6 - 8	11 July 1964
	dried fruits	insect disinfestation	+			1	15 February 1966
	dry food concentrates (buckwheat mush, gruel rice pudding)	insect disinfestation	+			0.7	6 June 1966
	poultry, eviscerated (in plastic bags) *)	radurization	+			6	4 July 1966
	culinary prepared meat products (fried meat, entrecote) (in plastic bags) *)	radurization	+			8	1 February 1967
	onions *)	sprout inhibition	+			0.06	25 February 1967
	onions	sprout inhibition	+			0.06	17 July 1973

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION			DOSE (k Gy)	DATE OF APPROVAL
			^{60}Co	^{137}Cs	electrons		
UNITED KINGDOM	any food for consumption by patients who require a sterile diet as an essential factor in their treatment	radappertization					1 December 1969
UNITED STATES OF AMERICA	wheat and wheat flour (changed on 4 March 1966 from wheat and wheat product)	insect disinfestation	+			0.2 - 0.5	21 August 1963
				+		0.2 - 0.5	2 October 1964
					5 MeV	0.2 - 0.5	26 February 1966
	white potatoes	sprout inhibition	+			0.05 - 0.1	30 June 1964
				+		0.05 - 0.1	2 October 1964
			+	+		0.05 - 0.15	1 November 1965
URUGUAY	potatoes	sprout inhibition	+				23 June 1970

COUNTRY (Organization)	PRODUCT	PURPOSE OF IRRADIATION	TYPE AND SOURCE OF RADIATION			DOSE (k Gy)	DATE OF APPROVAL
			^{60}Co	^{137}Cs	elec-trons		
WORLD HEALTH ORGANIZATION (FAO/IAEA/WHC Expert Committee)	potatoes **)	sprout inhibition	+	+		0.15 max	12 April 1969
	potatoes	sprout inhibition	+	+	10 MeV max	0.03 - 0.15	7 September 1976
	onions +)	sprout inhibition	+	+	10 MeV max	0.02 - 0.15	7 September 1976
	papaya	insect disinfestation	+	+	10 MeV max	0.5 - 1	7 September 1976
	strawberries	radurization	+	+	10 MeV max	1 - 3	7 September 1976
	wheat & ground wheat products **)	insect disinfestation	+	+	10 MeV max	0.75 max	12 April 1969
	wheat & ground wheat products	insect disinfestation	+	+	10 MeV	0.15 - 1	7 September 1976
	rice +)	insect disinfestation	+	+	10 MeV max	0.1 - 1	7 September 1976
	chicken	radurization radicidation	+	+	10 MeV max	2 - 7	7 September 1976
	cod & redfish +)	radurization radicidation	+	+	10 MeV max	2 - 2.2	7 September 1976

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*) experimental batches
**) temporary acceptance
***) hospital patients
****) test marketing
+) provisional
underlined: unlimited clearance (uncondtional acceptance: WHO)